

**MAGNITUDE AND ASSOCIATED FACTORS OF POST-DURAL
PUNCTURE HEADACHE IN SURGICAL PATIENTS AFTER
SPINAL ANAESTHESIA AT MOI TEACHING AND REFERRAL
HOSPITAL, ELDORET, KENYA**

BY

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SM/PGACC/01/17

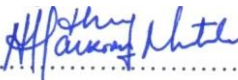
**A THESIS SUBMITTED IN PARTIAL FULFILMENT OF THE
REQUIREMENTS FOR THE AWARD OF THE DEGREE OF
MASTER OF MEDICINE IN ANAESTHESIA AND CRITICAL
CARE IN MOI UNIVERSITY**

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DECLARATION

DECLARATION BY CANDIDATE

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DEDICATION

This work is dedicated to all my teachers, my dear parents and my family. It is their invaluable mentorship, support and encouragement that have molded me into who I am today. I will forever remain indebted.

To my late mum Roda Kamonzi, you are the reason I have made it this far. Continue dancing with the angels dear!

ABSTRACT

Background: Post-dural puncture headache (PDPH) is a frequent complication following Spinal anesthesia with global incidence rates ranging from 0.3% to 40%, influenced by patient characteristics, clinician expertise and the type of equipment used. Although the use of spinal anesthesia is increasing at Moi Teaching and Referral Hospital (MTRH), local data on the occurrence and management of PDPH is limited. Therefore, understanding its incidence and associated risk factors is essential for improving care and outcomes.

Objectives: To determine the incidence, risk factors and management strategies of PDPH among patients receiving spinal anesthesia at MTRH.

Methods: This prospective observational study included 198 participants (aged 18 and above) who underwent surgery under spinal anesthesia at MTRH between August 2022 and January 2023. A standard G25 Quincke spinal needle was used in this study. Patients were recruited using a systematic sampling technique and followed at 24hrs, 48hrs, 72hrs, 7 days and 30 days post-procedure. Data on demographics, onset of headache and treatment were collected through patient interviews and review of medical records to complete a structured questionnaire. Analysis was performed using R software (version 4.0.0), with statistical significance set at $p < 0.05$.

Results: Participants' age ranged from 18-63 years with a mean of $31.2(\pm 9.9)$, with females comprising 72.7% of the sample. The overall incidence of PDPH was 23.7% (95% CI: 17.8-30.4), with most cases (65.9%) occurring within the first 24 hours post-surgery. 38.5% of patients experienced severe symptoms while 31.8% reported moderate symptoms. A significant association was found between PDPH and the number of puncture attempts factor ($p = 0.029$). Although Male gender ($p = 0.519$) and alcohol use ($p = 0.068$) were noted, they were not statistically significant. Most affected patients (81.8%) required analgesics, with Nonsteroidal anti-inflammatory drugs (NSAIDs) being the most commonly used treatment (43.2%). No epidural blood patches were performed during the study period.

Conclusion: PDPH is a common and clinically significant complication after spinal anesthesia at MTRH. The number of needle insertion attempts was a key risk factor in this study. NSAIDs were the primary mode of treatment, with no use of more advanced interventions like Epidural blood patch or nerve blocks.

Recommendations: Enhanced training for anesthesia providers is essential to minimize multiple puncture attempts. More research is required on risk factors associated with PDPH. MTRH should adopt a standardized PDPH management protocol, potentially incorporating combination therapies and exploring advanced techniques like epidural blood patches and nerve blocks. Further research into newer treatment options with better efficacy is encouraged.

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LIST OF ACRONYMS/ABBREVIATIONS

ASA	American society of anesthesiologists
BMI	Body mass index
C-section	Caesarian section
CSF	Cerebrospinal fluid
CT	Computed tomography
CVST	Cerebral Venous Sinus Thrombosis
EBP	Epidural blood patch
GABA	Gamma amino butyric acid
ICHD	International classification of headache disorders
IHS	International headache society
IREC	Institutional research and ethics committee
LP	Lumbar puncture
MRI	Magnetic resonance imaging
NRS	Numerical Rating Scales
PDPH	Post dural puncture headache
POD	Postoperative day
RCT	Randomized controlled trial
SPGB	Sphenopalatine ganglion block
VAS	Visual analogue scale

OPERATIONAL DEFINITIONS

Anaesthesia: Any medication given to induce sleep or to stop the transmission of pain impulses.

Atraumatic needle: A needle that does not cause injury to the Dura.

Diuretics: Drugs that accelerate urine output from the body

Epidural Blood patch: Injection of an analogous blood into the dural tear in order to repair it.

Epidural space: the area between the Dura mater (a membrane lining the spinal cord) and the vertebral wall

Euvolemia: State of having the normal volume of blood or fluids in the body.

In vivo: Happening in living organisms but not in tissues

Incidence: Incidence refers to the occurrence of new cases of disease or injury in a population over a specified period of time.

Intrathecal: Administration of drugs into the spinal canal, or into the subarachnoid space so that it reaches the cerebrospinal fluid (CSF)

Lumbar puncture: Insertion of a needle into the spinal canal for diagnostic, therapeutic or injection of a local anesthetic drug

Neuraxial: Local anesthetics placed around the nerves of the central nervous system, such as spinal anesthesia, caudal anesthesia, and epidural anesthesia.

Paramedian: Along the midline

Parenteral: Administered or occurring elsewhere in the body other than the mouth and alimentary canal

Parturient: Patient in labor about to give birth

Peridural: Around the Dura membrane

Post dural puncture headache: Postural headache that typically presents within the first 5 days of witnessed or suspected Dural puncture due to leakage of CSF after inadvertent Dural tear.

Postpartum: The period immediately after delivery

Radicular: Affecting or relating to the root of a spinal nerve

Regional anaesthesia: Use of local anesthetics to block sensations of pain from a large area of the body, such as an arm or leg or the abdomen

Spinal anaesthesia: Anaesthesia given locally by injection into the lower part of the spine

Spinal needle: A needle used to administer spinal anaesthesia

Stylet: A slender probe used as a guide.

Subarachnoid space: The space between the arachnoid membrane and the pia mater

Ultrasound: An imaging technique that produces real time images

Vasoconstriction: The narrowing of blood vessels

Vasodilatation: Increase in the diameter of blood vessels which leads to decreased blood pressure

Venesection: Removal of blood samples usually from a vein.

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CHAPTER ONE

1.0 INTRODUCTION

1.1 Background information.

Dural puncture is a technique done using a spinal needle to obtain Cerebrospinal fluid (CSF) for diagnostic or therapeutic purposes besides administration of spinal anaesthesia (C. Wu et al., 2018). It is done at the back between the lower lumbar vertebrae at the interspaces of the vertebral bodies either in a sitting or lateral position. Spinal Anesthesia (SA) on the other hand is the administration of a local anaesthetic agent in the subarachnoid space for surgical purposes. It is usually given in many surgical procedures in Obstetrics and gynecology, Urology, Orthopedic among other specialties to induce a peripheral block at the level of the spinal cord so that a good painless surgical field can be obtained.

Spinal anaesthesia was first introduced by the German surgeon Karl August Bier, in the year 1898 (Mackey, 2024). He was probably the first person to perform the procedure although many trials had been attempted before then (Edna Gisore, Mung'ayi, & Sharif, 2010)). Bier later had the procedure performed on himself and described an associated headache which was severe, associated with standing upright and relieved by lying in the supine position. This would later be described Post-dural puncture headache (PDPH) and he gained first-hand experience of the disabling headache related to dural puncture (Nuhu, Embu, & Shambe, 2017).

Notably, PDPH is a condition which occurs almost immediately after dural puncture, though the timing of occurrence is usually variable. Studies have shown that the condition can last for hours to days after inadvertent dural tear during Lumbar puncture, Spinal Anaesthesia or Subarachnoid drug administration (Bezov, Lipton, &

Ashina, 2010). Occasionally, the condition can even last for days to months though this is quite uncommon.

In the practice of anaesthesia, Spinal anaesthesia involving the injection of opioids, local anesthetics or other show that 62.9% of women in the United Kingdom, 61% in the United States of America, 58.7% in Canada and 79.3% of women in France give birth under spinal anaesthesia (Haller, Cornet, Boldi, Myers, & Kern, 2018). This shows that the demand for spinal anesthesia is high and will continue to grow progressively world over and therefore there is need to understand the possible complications, risk factors and interventions.

A multicenter prospective analysis conducted in China showed increased uptake of spinal anaesthesia. This increase could probably be due to associated multiple benefits such as better postoperative analgesia and lower morbidity and mortalities compared to general anaesthesia (Huo et al., 2016). However, despite its widespread use, spinal anaesthesia is not free of complications (Nuhu, Embu, & Shambe, 2017) like hypotension, Post-dural puncture headache, transient neurological symptoms among others. Other studies both locally and across Africa show similar trends. In addition, there has been an increase in the number of caesarean sections done in Kenya as compared to the recent past.

When lumbar puncture is done for therapeutic or diagnostic purposes, PDPH has been reported to be the commonest complications due to inadvertent dural tear, (X, Osorio, & X, 2015) and in fact, it was the commonest complication of spinal anaesthesia for a very long time before advancement in the conduct of spinal anaesthesia like the use of smaller spinal needles and modifications in the shape of the needle tip leading to significant reduction of the incidence. PDPH occurs typically twelve to twenty four

(12-24) hours after spinal anaesthesia (Kwak, 2017), and has a great impact on the recovery, hospital stay, comfort of patients after surgery hence posing a challenging situation for all anesthetists and surgeons (Pirbudak, Özcan, & Tümtürk, 2019)

The incidence of PDPH varies from hospital to hospital depending on both patient factors and procedural factors and from population to population. The exact cause of the condition is not fully known and this has been the subject for various investigations. There are also several documented risk factors to the development of PDPH, but the most plausible explanation on the pathogenesis is usually leakage of Cerebrospinal fluid (CSF) from an inadvertent dural tear during lumbar puncture. It is more common in young female patients, especially in obstetric surgeries as compared to other specialties (Bezov et al., 2010). On the other hand, the severity of PDPH pains can range from moderate to very severe pains, necessitating more advanced treatments modalities like epidural blood patch or surgical dural repair (Sachs & Smiley, 2014).

For instance, in the postpartum period, up to 39% of women experience headaches (Sabharwal & Stocks, 2011). However, not all headaches are attributed to PDPH even after spinal anaesthesia. It has actually been demonstrated that the postpartum headaches are due to; tension (39%), pre-eclampsia or eclampsia (24%), PDPH (16%), migraines (11%) and hemorrhage, thrombosis or vasculopathy (10%) (Chee & Lau, 2017).

PDPH poses a huge challenge in diagnosis and management since there is no specific diagnostic tool used to make a definitive diagnosis (Silberstein. S, 2005) The most commonly used diagnostic criteria is the classification according to the international headache society (IHS) which has been revised severally (Kracoff & Kotlovker,

2016). There are four main criteria for diagnosis of PDPH according to IHS. The four main elements of PDPH include the following; (I) A headache that develop within 5 days after dural puncture. (II) A headache that worsens within 15 minutes of sitting or standing upright and improves within 15 minutes after lying down. (III) A headache that is accompanied by at least one of the following symptoms: neck stiffness, nausea, photophobia, tinnitus and hypoacusia. (IV) A headache that resolves either spontaneously within one week or within 48 hours after effective treatment of the spinal fluid leak for instance with an Epidural blood patch or surgical repair of the dural defect (Road, 2013).

The headache usually resolves spontaneously though it may persist for several weeks hence necessitating intervention. In patients who develop PDPH, there is usually great fear while starting ambulation post-surgery and this may hinder rehabilitation and lead to prolonged hospital stay (Kayastha, Joshi, Kunwar, & Khadka, 2018). Under extended circumstances, PDPH has been shown to persist for more than 18 months after surgery. In a prospective longitudinal survey, (Gauthama, Kelkar, Basar, & Niraj, 2018) about 30% of those who developed PDPH after spinal anaesthesia had persistent headaches at 18 months. These results were indicative that PDPH should no longer be considered as a self-limiting condition, but rather as one of the complications of spinal anaesthesia during informed consent process. (Li, Wang, Oprea, & Li, 2022) recommends a staged approach to management of the condition.

In most instances, the headache due to PDPH is not only postural but also persist for more than 24 hours regardless of the severity and usually the patient is unable to maintain an upright posture (Russell et al., 2019). This therefore can significantly

interfere with the postoperative recovery of the patients who develop PDPH besides interfering with care of babies for breastfeeding mothers.

According to recent data, regional anaesthesia has now become the first line of choice for obstetric surgery, (Lotfy Mohammed & El Shal, 2017). All those modalities can have an associated CSF fluid leakage from the subarachnoid space and subsequent development of PDPH. The impact of the condition on patients cannot be underestimated and among diagnosed patients, about 39% experience at least 1 week of impaired ability to perform daily activities (Bezov et al., 2010). The complications of PDPH include chronic pain and also neurological sequel including the occurrence of cranial nerve palsies involving almost all the cranial nerves.

In obstetric surgeries, an international recommendation for safe motherhood and protection of the future mothers is to have 80-90% of all the Caesarian sections done under spinal anaesthesia. In the coming future, it can therefore be speculated that the number of Caesarean deliveries done under spinal anaesthesia will be on the rise. Among the anaesthetic options for surgical delivery, general anaesthesia administration in resource poor settings has been found to be more expensive than spinal anaesthesia (Kahveci et al., 2014), while epidural anesthesia though with more favorable outcomes, is much more expensive and requires more expertise to conduct as compared to spinal anaesthesia.

With those prospects therefore, more complications related to spinal anaesthesia especially PDPH which is debilitating and dehumanizing to the affected patients can be anticipated to keep on escalating into the future especially if proper preventive measures are not adhered to, (Nuhu et al., 2017). This will definitely be an area of growing concern as the number of spinal anesthesia procedures done go up, especially

in a teaching and referral hospital like MTRH, not forgetting that in Low and Middle-Income Countries (LMIC) like Kenya, we experience challenges in resources, supplies, clinical expertise and also equipment in most of our hospital settings.

1.2. Problem Statement

Post-dural puncture headache (PDPH) is one of the commonest complications of spinal anesthesia (Gaiser, 2017). In MTRH, anecdotal data and reports from patients and nurses in various wards have shown that there are still a significant number of patients who develop headaches after spinal anaesthesia. However, this has not been well documented as no single study has looked into the magnitude of the condition in our setting, therefore, whether the new onset headaches are related to PDPH or other causes of headache is not clear.

There is a decreasing trend of the global prevalence and incidence rates of PDPH in developed countries (Kracoff & Kotlovker, 2016) but on the contrary, higher estimates have been reported from developing countries most specifically from Africa. For instance, while a rate of <1% was reported in the United States and Singapore, studies from African countries have revealed a higher incidence, for instance, a study by (Nuhu et al., 2017) in a teaching hospital in Nigeria showed a prevalence of 22.03% while in Kenya, a study by (E. Gisore, Mung'Ayi, & Sharif, 2010) done at Aga khan hospital showed an overall cumulative incidence of 20.35%.

Much as the needle size, shape and orientation during the technique contribute much to the risk of developing PDPH, other patient and surgery related factors have been suspected and studied with conflicting results; however, these factors have not been well studied especially in the setting of MTRH.

MTRH is currently a training center for College of Anesthesiologists of East, Central and Southern Africa (CANECSA) and Master of Medicine (M. Med) in anesthesia in addition to the higher diploma in anesthesia (HND) and therefore more students on training are expected to administer spinal anesthesia as compared to the past. From MTRH theatre records, we note a consistent upward trend in the number of spinal anaesthesia techniques at MTRH over the years since 2017 as shown in the table below. On the contrary, MTRH currently lacks a standardized protocol on post-operative anesthesia care including active follow-up and management of patients who develop complications after spinal anesthesia.

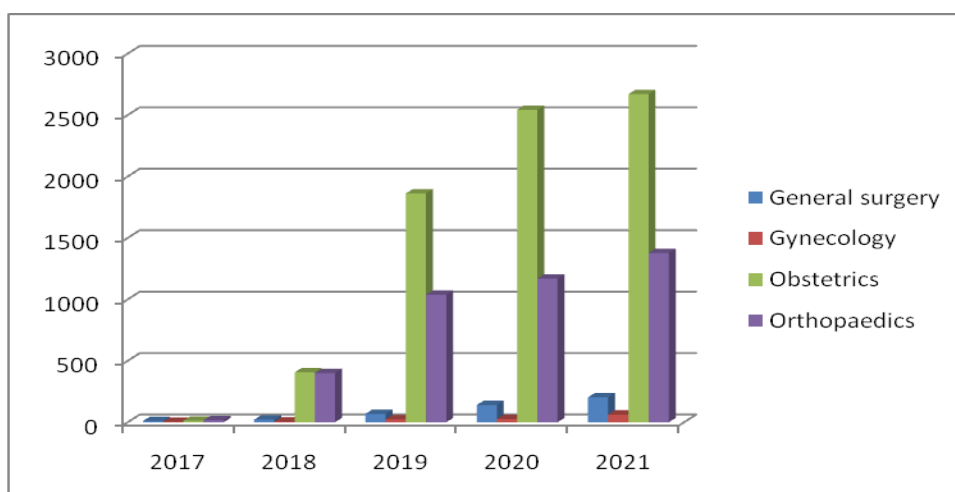


Figure 1: Spinal anesthesia techniques in MTRH from 2017-2021. (FROM MTRH Records)

1.3. Justification of the Study

Recent data has indicated that PDPH is still a major cause for concern in the developing world especially African countries (R.F et al., 2019). In addition, estimates of the prevalence and incidence rates as well as the associated risk factors of PDPH have not been able to be adequately documented from Africa (E. Gisore et al., 2010). Therefore, investigating the incidence of PDPH and associated risk factors using data from a teaching and referral hospital in Kenya will bridge the knowledge gap and provide additional data which is currently scarce in our setting.

The findings from this study will be used to highlight the burden of the problem in the local context and therefore inform the development of management protocols at MTRH which are currently deficient. Also, findings from this study will help guide preventive strategies both locally and regionally. Ultimately, the formulation of those clinical protocols will help improve patient outcomes.

Understanding the patterns of PDPH can help improve the training of anesthetists and other healthcare professionals in safe lumbar puncture and neuraxial anesthesia techniques since MTRH is affiliated to several training institutions for anesthesia providers. This can help development of guidelines on spinal anesthesia and post-puncture care, helping standardize practices across healthcare facilities in Kenya.

Lastly, local data can enable the institution to compare with regional, national or international PDPH rates and this can help assess the hospitals' performance and align it with best practices so as to ensure quality of services, especially now that the number of spinal anesthesia procedures is going up as revealed by MTRH records.

1.4. Research Question

What is the hospital incidence, associated factors and treatment modalities of patients with PDPH after spinal anesthesia at MTRH?

1.5. Objectives of the Study

1.5.1 Broad Objectives

To determine the hospital incidence, associated factors and treatment modalities of PDPH in surgical patients after spinal anaesthesia at Moi Teaching and Referral Hospital, Eldoret.

1.5.2 Specific Objectives

- To determine the incidence proportion of PDPH in patients after spinal anaesthesia at Moi Teaching and Referral Hospital.
- To analyze the associated factors for development of Post-dural puncture headache.
- To describe the treatment modalities of patients with PDPH at Moi Teaching and Referral Hospital.

1.5.3 Conceptual Framework of the Study

Following spinal anaesthesia, some patients will develop PDPH of varying severity. The risk factors include patient characteristics, procedure related factors and also factors related to the person performing the procedure. Management of PDPH is mainly dependent on the severity and involves both pharmacologic and non-pharmacologic modalities. After the various interventions, some patients report complete relief of the symptoms while others experience partial relief. However, some patients report treatment failure and persistence of symptoms occasionally for more than one month despite the common dogma that PDPH symptoms resolve spontaneously within one week.

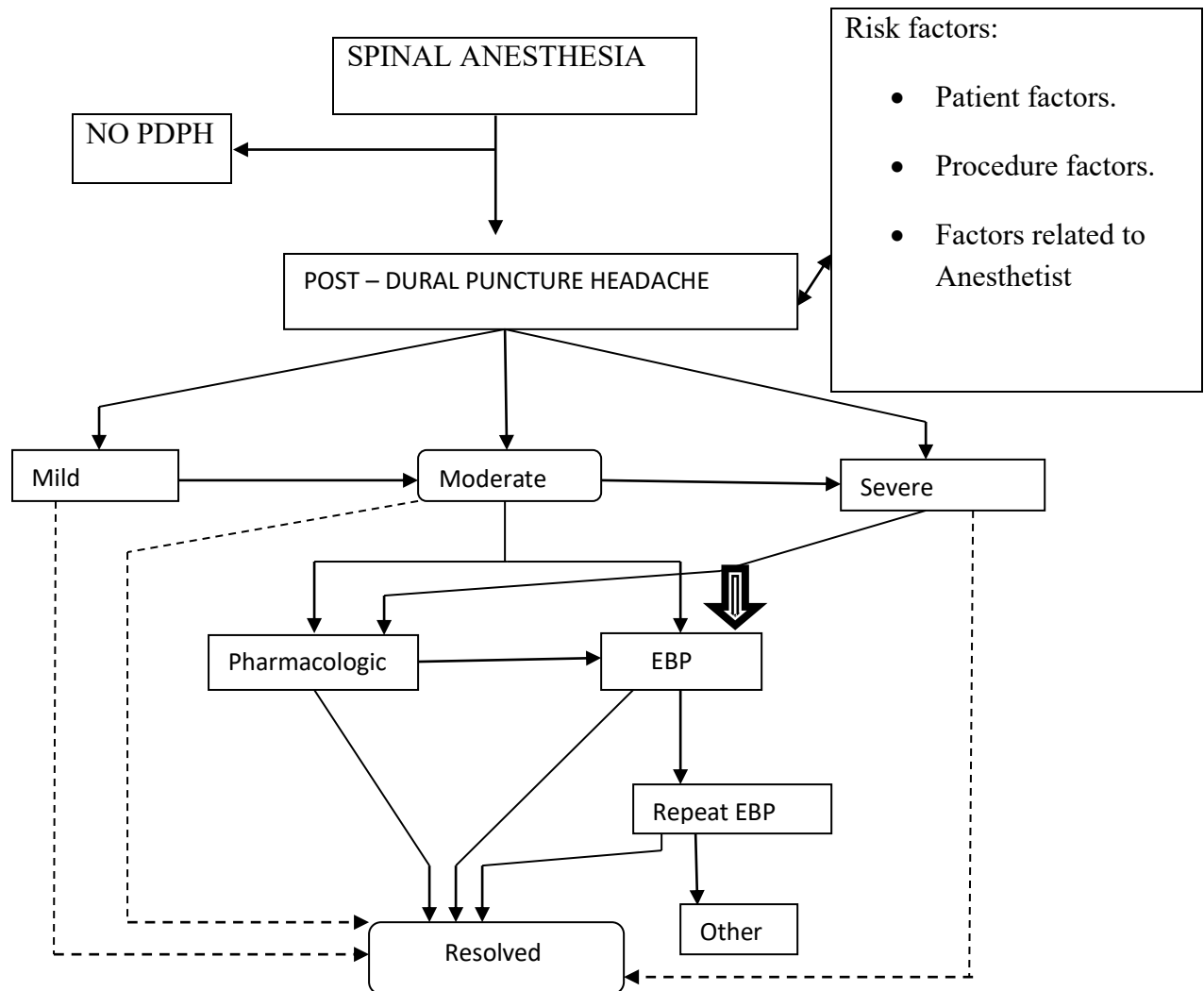


Figure 2: Conceptual framework of the study

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Introduction

This chapter comprises of review of literature on post dural puncture headaches (PDPH). It focuses on the historical backgrounds of post dural puncture headache, the risk factors and determinants for development of PDPH, Management (both supportive and definitive) and emerging issues in the field of spinal anaesthesia related to PDPH.

2.2. Historical background on PDPH

Spinal anaesthesia was brought into limelight around 1800s by Wynter, Quincke and Corning though the clinical significance was not realized until later on when Dr. August Bier advanced the idea (Turnbull & Shepherd, 2003). The first case of PDPH was recorded by a surgeon named Dr. August Bier in 1898 when he gave a personal account of the headache he experienced after spinal anaesthesia given to him. He further described the headache as a feeling of intense pressure in the head, accompanied by feeling of dizziness especially when rising quickly from a sitting position. In addition, he noted that all the symptoms were relieved markedly by lying flat and worsened by assuming the upright position (Chohan & Hamdani, 2003), (Nuhu et al., 2017a).

Before the discoveries of Dr. Bier, aspirated cerebrospinal fluid (CSF) from the subarachnoid space (Kracoff & Kotlovker, 2016) had actually been attempted. This was in an attempt to treat intracranial hypertension that was associated with tuberculous meningitis and causing increased intracranial pressures. Incidentally, all their subjects died soon after the procedure. Four years later in 1895, Corning

suggested a local spinal anaesthesia injection with cocaine to treat a patient who was addicted to habitual masturbation (Brown & Fink, 1998).

It was not until 1901 when a Swiss obstetrician used intrathecal cocaine injection to relieve the pain associated with the second stage of labour, that regional anaesthesia in obstetrics was popularized (Turnbull & Shepherd, 2003). During this time, the incidence of PDPH was above 50% and there were associated high obstetric mortalities which led to the abandonment of the technique in the 1930s-1950s (Turnbull & Shepherd, 2003). In order to reduce the prevalence and problem of spinal anaesthesia, several advancements have been made since the discovery of spinal anaesthesia. In 1951, Whitacre and Hart developed the pencil-shaped needle and the development in the needle design since then has seen a significant reduction in the incidence of PDPH (Andargie, E. 2018).

2.3. Incidence of PDPH

By 1898, the incidence of PDPH was as high as 66% which could mainly be attributed to use of large gauge spinal needles and also the traumatic aspect of the needles, Cutting type, as compared to pencil-shaped non-cutting type developed thereafter (Turnbull & Shepherd, 2003). Subsequently, the reported incidence rate from different settings has ranged between 1% and 70% but has considerably reduced following modifications in the design and size of spinal needles (Kayastha et al., 2018). In a randomized clinical trial, it was established that the incidence of distressing PDPH varied from <3% to around 75% from place to place and the greatest determinant was the needle size used (Lotfy Mohammed & El Shal, 2017). It has also been demonstrated that the rate of PDPH is not constant and varies from 0.1%-36% depending on several factors (Azzi et al., 2021), (Jabbari et al., 2012)

In one study, it was noted that the incidence rate was 3.1% when 25G Whitacre needle was used (the non-traumatic needle) and as high as 25% when 25G of the popular cutting type needle, Quincke, was used (Jabbari, Alijanpour, & Mir, 2013)

The incidence of PDPH varies from place to place depending on the risk factors, the technique and conduct of the spinal anaesthesia. Studies conducted on the obstetric population reported that the incidence of inadvertent dural tear leading to PDPH was 0-2.6%, and that following a dural tear, the incidence of PDPH was estimated at 50% to 85% (Chee & Lau, 2017). However, the same study showed that PDPH can still occur even where there is no identified dural puncture.

According to a study done at Aga Khan Hospital in Nairobi, Kenya, the cumulative incidence in obstetric patients following Caesarian section under spinal anaesthesia was 20.35%. However, the incidence was significantly higher in patients in whom the Quincke type of needle was used than in the non-cutting pencil shaped spinal needles (24.2% versus 4.5% respectively). In addition, the type of spinal needle used was influenced by many factors including availability and also the preference of the specific anesthetist (Edna Gisore et al., 2010).

In Congo, the reported prevalence of PDPH was 27.5% according to a prospective study by (R.F et al., 2019). These results affirmed results from previous studies which suggested that PDPH could actually be a problem in the developing world. The authors further stated that the determinants of PDPH can also be stratified and used to develop simple and reliable predictive scores to enable proper screening, diagnostic orientation and formulation of reproducible prophylactic regimens (Iteke et al., 2019).

In a recent study at a tertiary hospital in Nigeria, a prospective study in obstetric patients showed that the prevalence was 22.03% (Nuhu et al., 2017a). These results

show a high figure though comparable to other findings from developing countries. Results from the same study shows that most of the patients who developed PDPH had mild to moderate symptoms based on the numeric rating scale (11%-mild and 4.7%-moderate intensity of headaches), and this compares with a recent study by (Gupta et al., 2020) which showed that most of the headaches are of the mild form. Notably, all the cases in that study resolved with adequate treatment which involved mainly conservative modalities.

Another prospective study done in Nigeria showed that all the cases of PDPH occurred during the first 24 hours and were of mild to moderate severity based on the Visual analogue scale (VAS). The cumulative incidence rate of PDPH was reported at 15.8% and was lower in those who used the atraumatic pencil tipped needles (Lotfy Mohammed & El Shal, 2017). In DR Congo, the prevalence of PDPH was reported at 27.5% by a recent epidemiological study conducted by (R.F et al., 2019). Contrary to these findings from Africa, there has been a downward trend on the global prevalence of PDPH from 66% in 1898, 11% in 1956 and recently fell to 1-4% (Iteke et al., 2019). The incidence appears to be much less in more developed countries in Africa hence pointing at the possibility of socioeconomic status being one of the determinants. One study done in South Africa showed 3.4% incidence among obstetric patients (Jacobs-Martin, Burke, Levin, & Coetzee, 2014).

The figures recorded in developed countries are much lower and whether this is a problem of developing countries is beyond the scope of this study. In Canada for instance, the rate of accidental dural tear are between 0.5%-4% and this is associated with acute or chronic morbidities including PDPH. However, even in developed countries, the incidence is dependent on the size of needle used such that the smaller

the needle's tip, the lower the incidence. In Italy, a study from a diagnostic lumbar puncture procedure showed almost similar results and the incidence of PDPH was 35.9% when 20G Quincke needle was used and 12.9%, 6.8% and 1.6% when 22G Sprotte, 25G Whitacre and 25G Sprotte needles were used respectively (Bertolotto et al., 2016). This is actually not so far from what has been demonstrated in the African population. Also, the incidence of PDPH is dependent more on the size of the needle rather than the shape of the needle as demonstrated by (Maranhao, Liu, Palanisamy, Monks, & Singh, 2021) but this comes with a challenge in that the smaller the needle size, the higher the probability of procedure failure especially if smaller than 26G needles are used.

In Karachi, the incidence of PDPH varied from 0.1%-36% with the highest incidence (36%) found with 20-22gauge standard Quincke spinal needle (due to big size and cutting caliber). In addition, unintentional dural puncture with large Tuohy needle (16 and 18 gauge) was associated with a much higher PDPH incidence of 70-80%. These results hence showed that reducing the diameter and caliber of the spinal needle can greatly reduce the incidence of PDPH (Chohan & Hamdani, 2003). It has also been demonstrated that the incidence of PDPH is much lower when the paramedian approach is used as compared to the midline approach (Nasir, Mahboob, Mehmood, & Haider, 2020)

In another study, double blinded randomized trial, PDPH occurred in 31.7% of patients using 22G spinal needle, 11.7% in patients using 25G needle and 0% in patients using 29G Quincke needles (Lotfy Mohammed & El Shal, 2017). These findings depicted the efficacy of spinal needle size in the reduction of PDPH. However, the study concluded that it was much more time consuming to give spinal

anaesthesia with 29G needle than with the other needles. It therefore appears that the needle gauge is more important in determining the incidence of PDPH as compared to the needle shape. However, this contradicts another study which showed that the likelihood of developing PDPH was higher in cutting type needles as compared to pencil-shaped needles but there was no major difference when different gauges of the pencil-shaped needle were used (Zorrilla-Vaca, Mathur, Wu, & Grant, 2018). This is thus an area where more research is needed especially to compare different sizes and gauges of spinal needles.

According to a prevalence study conducted in Central Nigeria comparing 23G, 25G AND 26G Quincke needles, the results showed that the highest incidence was with the 26G needle, which is the smallest, compared to the rest. These results were surprising and contravened the findings of other previous studies (23G=23.26%, 25G=15.67%, 26G=26.93%) (Nuhu et al., 2017). However, this could have been due to smaller number of patients who used size 26G as compared to the other needle sizes. Further, from this same study, it was concluded that different results would have been observed with an increased sample size for all needle sizes.

At a military hospital in Pakistan, the incidence of PDPH was established to be quite variable depending on the needle size ranging from 40% for 22G, 3-25% for 25G, 2-12% for a 26G Quincke needle and <2% for a 29G needle. These results were indicative that using progressively smaller needles can markedly reduce the risk of PDPH. However, the smaller the needle size, the higher the rate of failure of spinal anaesthesia. In addition, other risk factors for development of PDPH were multiple attempts during procedure, female sex, younger age group and obstetric population (Riaz, Khan, & Sharif, 2014).

The incidence of PDPH is the same in all the surgery categories (Obstetrics and gynecology, urology, orthopedics and general surgery although it is more frequent in patients undergoing delivery (Jabbari et al., 2013). The same study showed that there was no difference regarding incidence of PDPH between emergency and elective cases or even daycare surgeries.

With the use of small standard spinal needles, an incidence rate of 0%-14.5% was reported and was associated with some extent of CSF leakage from the dural defect and intracranial hypotension (Castrillo et al., 2015) though the incidence is much higher when larger spinal needles are used, which compares with most of the other studies investigating relationship between needle size and incidence of PDPH. According to (Omole & Ogunbanjo, 2015), the incidence of PDPH in South Africa decreased from above 50% to about 2% with more recently designed 29 gauge pointed needles.

In a tertiary hospital, a study conducted in Ethiopia, showed that the incidence of PDPH in elective C/S mothers following spinal anaesthesia was 38.7% and there was a very strong association between the needle size and PDPH. The orientation of the needle bevel perpendicularly to the longitudinal dural fibers rather than parallel orientation and multiple dural puncture attempts during administration of spinal anaesthesia were also associated with higher risks of development of PDPH (Andargie, E. 2018).

Different results have been reported when the spinal needles of the same sizes were used but varied by shape of the tip-either pointed or cutting type needles. An incidence rate of 6.5% in those who used 26G Atraucan needle compared to 4.98% in those who used 26G Quincke needle in a randomized double-blind study conducted

on 682 women having elective cesarean section. The results from this study confirmed the argument that the shape of needle at the tip and also technique of spinal anaesthesia including the orientation of the bevel among other factors usually influence the development of PDPH (Akdemir et al., 2017).

A recent RCT study in parturient patients who had caesarian deliveries under spinal anaesthesia as compared to general anaesthesia showed that about 11% of those who received spinal anaesthesia developed PDPH (Abdelaal et al., 2018). However, the study did not establish whether there were any reported cases of PDPH in those who received general anaesthesia. Further, it was noted that 3.5% of those who did not develop PDPH (due to failure to meet the threshold for PDPH criteria as per the ICHD-1) had headaches with a VAS score of ≥ 5 . A few were excluded from the study due to history of migraine headaches.

In a root cause analysis study done in Geneva, PDPH following trauma to the dural membrane during spinal anaesthesia occurred in 0.13%-6.5% of pregnant women (Haller et al., 2018). This figure is actually lower compared to the current statistics reported from resource limited settings. In contrast, they noted that effective training of personnel for more than 3 years and the presence of a nurse anesthetist during the procedure decreased the risk. However, the anesthetist's identity, the size of the labour room, timing of the procedure or workload did not have any influence in modifying the risk for PDPH. Therefore, the development of PDPH in this setting was not a result of the individual anesthetist's characteristics alone, but rather a combination of factors. Thus, improvement strategies should consider all the other factors involved in order to reduce the incidence of PDPH.

In developed countries like the United States, the incidence has been reported to be as low as 1% with typical obstetric anaesthesia (Kracoff & Kotlovker, 2016). This is thought to be due to the advancements in the spinal anaesthesia techniques and adequate training of the personnel. However, in other countries like China, the incidence is quite higher. For instance, in one research the incidence was reported to be 10-33% (Beek & Brouwer, 2017). Incidentally, despite the strong evidence on the benefit of using non-traumatic needles, there is still low uptake even in the developed world. A study in two French hospitals revealed that non-cutting needles were used only in 8% of the cases despite their availability. We can then argue that this is related to the anesthetist's expertise; one would prefer to use what they are comfortable with or maybe the physicians are not convinced by the evidence of use of those non-traumatic needles.

One of the studies that provided further evidence of a declining trend as a result of training and proper supervision of the epidural procedures is a retrospective audit over a nine-year period at a tertiary teaching hospital in Singapore reported an overall incidence to be 0.15% (Tien et al., 2016). This figure is quite low compared to others studies probably because of proper preventive measures and training of the clinicians or even an issue with reporting of the events. However, the results revealed that the incidence was 67.2% after accidental dural puncture. This strongly supports the theory that the pathogenesis of PDPH is directly related to presence of a dural tear.

Some literature suggests that placing an intrathecal catheter for up to 24 hours after spinal anesthesia or lumbar puncture reduces the risk of PDPH. It is postulated that the catheter seals the dural tear and enhances an inflammatory response which helps to close the hole and hence prevent the leakage of CSF. The catheter also gives the

benefit of injecting post-operative analgesia, negating the need for repeated dural punctures (Kwak, 2017). Another preventive measure is also epidural saline injection which helps to reduce the pressure gradient between the epidural and subarachnoid space therefore lowering the amount of CSF leakage. In addition to the debilitating effects of PDPH, there are also other associated complications of spinal anaesthesia like difficult in bladder voiding. All these factors hinder early mobilization especially in patients who receive spinal anaesthesia for lower limb surgeries. Strict bed rest and supine positioning has been shown to significantly reduce the occurrence of PDPH (Kayastha et al., 2018)

2.3 Associated factors for development of PDPH

There are many factors that have been documented as determinants for development of PDPH. However, there is no single factor that has been found to be the sole risk factor. Issues to do with gender, type of surgery, needle size, procedure technique, patient factors among others have been documented in various studies. According to (Riaz et al., 2014), the main factor that determines the frequency of PDPH is the needle size and design. It has therefore been established that use of a larger needle increases the risk of developing PDPH. Also, use of the cutting type needles increases the risk for development of PDPH.

Regarding the non- modifiable risk factors, PDPH risk is twice in women and occurs more in young people (Bezov et al., 2010). The reasons for the female gender predominance are not well understood. There is no documented preference in terms of race. According to one study, (Peralta, Higgins, Lange, Wong, & McCarthy, 2015), the incidence of PDPH is low in parturient patients with an increased body mass index

(BMI). However, the severity and need for epidural blood patch administration was similar for all the BMI groups studied.

It is worth noting that previous studies have revealed contradicting results regarding the association between BMI and development of PDPH. While (Nduku, Jackson, & Wambui, 2023) and (Osman et al., 2023) showed an increased incidence with increasing BMI levels, (Peralta et al., 2015) demonstrated that lower BMIs were associated with increased risk of developing PDPH.

According to (Ri, 2019), patients between the age of 25 to 40 years and patients undergoing CS operations experience headaches more frequently in the postoperative period. However, this does not mean that all the headaches meet the criteria for diagnosis of PDPH. The exact cause of PDPH is not known but the risk factors are well established and documented. However, most of the data is actually from developed countries and there is paucity of data in the third world countries (E. Gisore et al., 2010). Further, it is quite notable that most of the studies have been done in the obstetric population and therefore few comparison studies have been done in other specialties where spinal anaesthesia has been done.

PDPH is a common complaint after inadvertent dural puncture and the risk factors range from type and duration of surgery, position of the patient during the spinal procedure, type and shape of needle used and the immobilization time on the operating table (Abdelaal et al., 2018). The main risk factors that influence development of PDPH include characteristics of the patient population, nature of the needle used and the puncture technique (Chohan & Hamdani, 2003). In addition, it was found out that the incidence of PDPH in the same study is highest between 20-40yrs of age but decreases with advancing age and least common above the age of

65yrs of age. This is consistent with the results of literature review by (Jabbari et al., 2013).

In the same study, it was reported that women are more likely to be affected than men at a rate of 14% in women as compared to 7% for men. To avoid any bias as a result of having more women in the obstetric group than men, patients in this category were excluded from analysis and it was established that women still had the highest incidence of about 12% compared to men 7% (C. L. Wu et al., 2006)

Parturition also accounts for the highest number of cases of PDPH. Incidence in those patients has been reported to be as high as 38% but in most of the studies it varies from 0%-30% (Chohan & Hamdani, 2003). This is attributed to the increased cerebrospinal fluid (CSF) pressure related to pregnancy, dehydration, associated blood losses during delivery, postpartum diuresis, hormonal imbalance, increased serum estrogen levels and also high peridural pressure (Akdemir et al., 2017). The needle size and the technique (orientation of the needle bevel) have been shown to be the other common risk factors (Akdemir et al., 2017). In terms of the age, young adults are at higher risk of developing PDPH than older individuals (14% vs. 7%) (Kwak, 2017).

It has been proposed that needle tip deformation due to contact with bone during insertion could lead to an increase in the diameter of the dural tear, hence more CSF leakage due to a large dural perforation. It has been demonstrated in vivo that the cutting type needle are more likely to be deformed as compared to the pencil-tipped needles (Turnbull & Shepherd, 2003). Some other risk factors, though important determinants of PDPH have not been well documented in literature. A descriptive and analytical observational study done in Congo noted that advanced age ≥ 35 years of

age, overweight, prior spinal anaesthesia, parity 1 or ≥ 5 , the degree of urgency of the procedure, L2-L3 puncture levels and also more than 3 puncture attempts contribute significantly to the development of PDPH (Iteke et al., 2019).

The morbidity of PDPH is more common in young females and is said to be also related to the needle size and shape. It is postulated that the bigger the needle, the higher the risk of developing PDPH and vice-versa. It is also known that the incidence is much higher when using the cutting type as compared to the sharp-pointed non-cutting spinal needles. Actually, the higher the CSF leakage, the higher the chances of developing PDPH, of coz depending on the volume lost from the subarachnoid space (Nuhu et al., 2017a). In a separate study, younger women and those with lower BMI were showed to have a higher incidence due to their fiber elasticity that maintains a patent dural defect compared to decreased elasticity in older age (Kracoff & Kotlovker, 2016).

Among factors that do not have a significant role in the development of PDPH according to a review of literature are underlying diseases like diabetes mellitus, high blood pressure, lung diseases like COPD especially if there is good control of the underlying disease condition (Jabbari et al., 2013). From the same review of literature, they noted that there was an inverse relationship between the level of experience of the person administering the spinal anaesthesia and the incidence of PDPH. However, it has been found that smoking and use of caffeinated drinks increases the risk for PDPH (Ljubisavljevic, Trajkovic, Ignjatovic, & Stojanov, 2020). This compares with the results of other studies that have investigated the risk factors that determine the development of PDPH and possible preventive strategies. The risk factors documented include low body mass index, female gender and young age below 30

years. Preventive measures which are effective include smaller gauge needles, non-traumatic needles and less CSF leakage during spinal anaesthesia and lumbar puncture.

Among some of the studies which have compared obstetric and non-obstetric procedures, the findings have yielded similar results. Subgroup analysis shows that there is a significant correlation between needle gauge and rate of PDPH. While there is evidence of relationship between needle gauge and the cutting-shaped needle design, a similar association was not actually shown for the pencil-shaped needle design (Zorrilla-Vaca, Healy, & Zorrilla-Vaca, 2016). The results of this study suggested that provided the pencil-shaped needle is used to administer spinal anaesthesia, the gauge size does not significantly determine the incidence of PDPH. On the other side, 1-gauge increase in the cutting-type needles led to subsequent reduction in PDPH by nearly around 3% (Zorrilla-vaca, Mathur, Wu, & Grant, 2018). Comparison studies involving the non-traumatic needles and the conventional type needles have shown similar results. From a meta-analysis (Nath et al., 2017), PDPH occurred in 11% of patients in the conventional group compared to 4.2% in the non-traumatic needle group.

Many scholars have tried to investigate other possible risk factors. There are arguments that the incidence of PDPH could be increased by abnormal anatomy of the spine. However, this may not be true as demonstrated in some studies. (Barrett, Arzola, Krings, Downey, & Carvalho, 2018), conducted studies of the lumbar spine anatomy using Ultrasound imaging and confirmed by M.R.I, and compared those who developed PDPH and the rest of the study subjects who did not experience post dural puncture headache. They had very experienced clinicians administer the spinal

anaesthesia. They noted that dural punctures and subsequent PDPH occurred in typically in anatomically normal women.

Nevertheless, there is still emphasis on use of non-traumatic needles given the available evidence. In order to avert harm from patients, a change of practice is required given the strong evidence of prevention when non-traumatic needles are used (Nath et al., 2017).

The occurrence of PDPH is rare in children (Raiger, Naithani, Gupta, & Pareek, 2019) and there is conflicting data on the modifiable risk factors, preventive measure and treatment modalities though many literature have quoted age, gender, needle diameter, needle tip design, orientation of the tip during puncture, previous history of PDPH, previous history of migraines and repeated attempts during the procedure (Janssens, Aerssens, Alliët, Gillis, & Raes, 2003).

It has been shown that there is a relationship between work time period and the development of PDPH. One study which compared the time of work and incidence of PDPH revealed that the incidence was higher in on-call period like nights and weekends as compared to spinal anaesthesia done during the day (40% and 21.6% respectively), (Khraise, Qudaisat, Amarin, Hawary, & Allouh, 2017).

2.4. Management of PDPH

Management of PDPH includes both conservative and definitive management. Even without any intervention, it has been reported that about 85% of post dural puncture headaches will resolve in less than 6 weeks post-surgery (Conn, Datta, Derby, & Schultz, 2009). The management of PDPH depends entirely on the severity of the headaches and therefore management is mainly individualized on case-to-case basis.

Further, it depends on the skills of the attending clinician and in some instances referral is necessary for epidural blood patch (EBP), (Turnbull & Shepherd, 2003).

PDPH is usually self-limiting and treatment is usually indicated when the symptoms persist or in severe cases. Conservative treatment includes bed rest, hydration, positioning, abdominal binders, analgesics and other drugs like caffeine, methylxanthine, theophylline and cerebral vasoconstrictors (Chohan & Hamdani, 2003). However, in severe cases, definitive treatment is indicated which includes epidural saline, epidural dextran and epidural blood patch. The pharmacologic treatment for PDPH include caffeine, theophylline, sumatriptan, normal saline and dextran among others (A. Choi, Laurito, & Cunningham, 1996). There is no specific treatment for PDPH and therefore supportive measures like hydration, bed rest, caffeine and non-steroidal anti-inflammatory drugs (Nuhu et al., 2017a) remain the mainstay for treatment of PDPH. Usually, about 16% of the cases will respond to conservative management without the need for an invasive procedure. Therefore, EBP is usually indicated in more severe and persistent cases (Gauthama et al., 2018). Unlike other previous studies, a Cochrane review of previous studies showed that there was no significant evidence showing that routine bed rest and administration of intravenous fluids were beneficial in the prevention of PDPH (Ciapponi, M, Muñoz, & X, 2016).

There exists no single standard evidence-based treatment for PDPH and many treatment modalities have been attempted in different centers showing different degrees of effectiveness. For instance, addition of neostigmine and atropine to conventional treatment of PDPH in a randomized controlled study by the same authors was noted to be effective enough after 2 doses of treatment. The combination of atropine and neostigmine actually reduced the need for EBP to zero in those who

had been scheduled for the procedure. This is argued to be due to effects of neostigmine and atropine in influencing both CSF secretion and cerebral vascular tone which are the primary pathophysiological changes that lead to the development of PDPH. However, the two regimens have been associated with side effects like abdominal cramps, muscle twitches and urinary bladder hyperactivity (Abdelaal et al., 2018).

Another new development in the treatment of PDPH is the use of hyperbaric oxygen therapy (HBOT) immediately after suspected accidental dural puncture to minimize the risk of developing PDPH. The rationale for the use of HBOT is postulated to be increased fibroblast proliferation at the site of the dural puncture, which helps in healing and closure of the dural tear, hence reducing the incidence of PDPH. This is therefore effective as a prophylactic therapy before onset of the syndrome. Prevention of PDPH can be done by modifying the known risk factors by prophylactic blood patches, lateral orientation of the needle bevel when performing the procedure, using the non-cutting pointed needles, giving epidural morphine after spinal anaesthesia and also administration of cosyntropin (Kracoff & Kotlovker, 2016). However, there is no single remedy that has been found to be solely effective.

The treatment for the first 24-48 hours does not need definitive treatments and should remain supportive as much as possible including bed rest, oral analgesics that do not diminish platelet function such as opioids like morphine, and adequate hydration to maintain euvolemia. Other treatment modalities that can be used include gabapentin which increases the levels of the inhibitory neurotransmitter Gamma Amino butyric acid (GABA) and also cosyntropin, an analogue of ACTH, which is postulated to

increase the secretion of CSF into the subarachnoid space (Kracoff & Kotlovker, 2016).

The treatment goals are usually to reduce the dural defect hence decreasing the leakage of CSF or to increase CSF production. The efficacies of many therapeutic drugs have been investigated with noted varied results. The efficacy of aminophylline for instance, in the treatment of PDPH is good and has been found to significantly lower the mean VAS scores after 8 hours of treatment. In addition to the good efficacy, the therapeutic effects have been noted to start 30 minutes after administration and lasts for about 2 days with enhanced control. There has not been noted enhanced side effects in those treated with aminophylline (C. Wu et al., 2018).

As much as there have been several advancements in the conduct of spinal anaesthesia, it has not yet been documented on the efficiency and safety of EBP. Many studies have been done to investigate this conundrum but the results are confusing and conflicting. Several studies suggest that Epidural blood patches are effective and long lasting for many patients but they increase the risk of other complications like epidural infections, transient or persistent neck and back pains, radiculopathies and other signs of meningeal irritation. This is because it is an invasive procedure (C. Wu et al., 2018). The theory behind the mechanism of EBP in the treatment of PDPH is supported by the experiments done by Gormley in the 1960s who noted that the patients who had bloody taps were less likely to lead to PDPH. This is because blood clots attract other inflammatory cells like platelets, leucocytes and fibroblasts which accelerate the healing process and hence the final repair of the dural tear (Turnbull & Shepherd, 2003).

If oral analgesics are not effective enough to treat the post dural puncture headaches, then the alternative is to use epidural, intrathecal or parenteral opioid analgesics like morphine or fentanyl but the definitive treatment would be to use EBP or fibrin glue to seal off the dural tear. In some very rare instances, those interventions may not work necessitating surgery for closure of the dural perforation (Turnbull & Shepherd, 2003). The effectiveness of EBP in treatment of PDPH still remains a matter of debate and the factors that lead to its failure are not well established (Safa-Tisseront et al., 2001). The results of this study showed that EBP is effective and most of the patients experience a complete resolution of the symptoms. They also noted that the effectiveness is reduced if there is a delay in treatment or when PDPH is caused by a large bore needle. Complete or partial relief of the symptoms has been shown to occur in 50-80% of the cases (Nhs & Trust, 2019).

Recommendations from a narrative review by (Nhs & Trust, 2019) propose the use of protocols and guidelines for performing the EBP since if not well performed, then high quality evidence of the effectiveness of EBP is limited. Issues like timing, positioning following an EBP and current guidelines of performing an EBP need to be considered. In addition, those who receive the EBP need to be reviewed by an anesthetist within 4 hours after the procedure in order to assess the progress. In fact, the efficacy of EBP has been challenged by the findings of (Gauthama et al., 2018), who noted that 43% of those who received EBP still sustained persistent headaches after the procedure. Some of the factors noted to predispose to the chronicity of headaches include history of migraines, chronic body pains, history of anxiety and depression.

In terms of preventive measures for PDPH, many strategies have been tried in different centers for instance hydration with supplemental intravenous fluids and prophylactic epidural blood patches but have not been found to be effective (Beek & Brouwer, 2017). Consequently, in as much as bed rest is an effective therapeutic measure, it has not been found to be effective in prevention after spinal anaesthesia. Another review by (Long, 2017) has comparable results, and further strengthens the argument that neither bed rest nor supplemental fluids decrease the incidence of PDPH.

Currently, skills acquisition on how to administer spinal anaesthesia is one of the ways on how prevention can be realized. One of the training programs that has been adopted is a well-structured epidural training program with an epidural trainer model, before an anesthetist can be accredited to perform the procedure. This model has been adopted in Singapore with significant reduction of the complications of spinal anaesthesia like PDPH (Tien et al., 2016).

The efficacy of epidural dexamethasone in prevention of PDPH after spinal anaesthesia has been demonstrated by several randomized controlled trials (RCTs). (Tehreem, Jahangir, & Ahmad, 2018) demonstrated that the rate of post dural puncture headache was higher in the control group compared to the intervention group 12.96% and 5.56% respectively, where prophylactic dexamethasone was administered as an adjuvant during spinal anaesthesia. Therefore, this can be applied as an effective intervention in those patients who undergo spinal anaesthesia. The dose of dexamethasone given was 8mg in all the subjects.

Zolmitriptan, a drug specifically used for the treatment of migraines has been shown to be effective in addition to other supportive treatments, in the treatment of PDPH. In

a RCT 60% of the patients who got Zolmitriptan were free of headaches as compared to only 36.6% in the control group after 6 hours. At 24 hour review, 96.66% and 63.33% of patients who got Zolmitriptan as compared to controls respectively were free of headaches and subsequently there was no change in results after 72 hours in those who received zolmitriptan (Riaz et al., 2014). This showed that zolmitriptan is effective initially in the control of severe PDPH.

In a Cochrane review done by (X et al., 2015) which considered RCTs assessing the effectiveness of all the pharmacological drugs used for treating PDPH e.g. oral and intravenous caffeine, subcutaneous sumatriptan, oral gabapentin, oral pregabalin, oral theophylline, intravenous hydrocortisone, intravenous cosyntropin and intramuscular adrenocorticotrophic hormone (ACTH), there was lack of evidence for some the treatment options assessed (sumatriptan, adrenocorticotrophic hormone, pregabalin and cosyntropin). However, they noted that consistent with the previous review, caffeine was noted to be effective in reducing the number of participants who needed supplemental treatments; gabapentin, hydrocortisone and theophylline were shown to decrease pain severity scores.

It has also been documented that replacement of the stylet before the removal of the needle reduces the incidence of PDPH (Janssens et al., 2003), the exact mechanism is not well known but a possible explanation is that during the procedure, a strand of arachnoid mater may enter the needle with CSF and when the needle is removed, the strand may be drawn back through the dural defect hence preventing the CSF leakage.

In terms of the approach during the administration of spinal anaesthesia, one of the ways to prevent or reduce PDPH is by use of the paramedian approach as compared to the median approach. However, there are conflicting results on the statistical

significance in terms of the difference in frequency of PDPH between median and paramedian approaches (Firdous, Siddiqui, & Siddiqui, 2016). Prophylactic analgesics may not be effective in the prevention of PDPH once unintentional dural tear has occurred during spinal anaesthesia. A recent study by (Brinser et al., 2019) showed no benefit of giving neuraxial morphine as a preventive measure. It was also noted that neuraxial morphine was not associated with significant decrease in headache severity and did not decrease the need for EBP. The results however agree with some but also disagree with some previous published studies hence the need for more trials in the future.

Epidural blood patch is associated with complications like radicular pains due to inflammatory responses and also nerve root compression. That necessitates the need for other alternatives with fewer side effects. A retrospective survey of the treatment of postpartum patients revealed that sphenopalatine ganglion block (SPGB) was more superior to EBP in terms of pain relief and also had fewer side effects. In the study, there were no complications in those patients who received SPGB while none of them returned to the emergency room after treatment as compared to those who received EBP (Cohen et al., 2018).

The incidence of PDPH can greatly be reduced by use of various strategies. As we continue seeing more technological advancements in medicine like image guided procedures, one may guess that Ultrasound or CT guided spinal technique will be the method of choice in order to reduce the already known complications of spinal anaesthesia. This however is an area that needs more research since there is paucity of information, though we can predict that larger studies with ultrasound guided

neuraxial blockade may reveal a definite path towards minimizing the incidence of PDPH if not completely eliminating the complication.

According to (Ismail, S. 2019), ultrasound guided neuraxial blockade offers a safe, non-invasive, without-radiation exposure, easy to use and provides real time images. It is especially beneficial in those patients where the traditional palpation identification of the insertion site is compromised by such factors as atypical spine like scoliosis and difficult situations like obesity and pregnancy. It is estimated that the global success rate of spinal needle insertion in the first attempt is 61-64%. In addition, failure at first attempt is attributed to difficult landmarks as a result of obesity, spine deformities among others. It was observed that using ultrasound imaging, a success rate of 84% was achieved in the first attempt. Since the incidence of PDPH is directly related to the number of attempts, the use of ultrasound guided techniques can therefore markedly reduce the disease burden (Bajwa & Sharma, 2015).

However, recent studies have demonstrated a growing gap in the associated factors for development of PDPH and also there is increasing lack of evidence in some of the treatment modalities that have been used over years for instance oral caffeine. Few studies have also evaluated the efficacy of some of those modalities. However, new treatment modalities like nerve blocks have been shown to be more effective though few studies have been done locally. Therefore a knowledge gap still exists in the risk factors and management of PDPH in our setting.

CHAPTER THREE

3.0 RESEARCH METHODOLOGY

3.1 Study site

The study location was at the Moi Teaching and Referral hospital. MTRH is in Eldoret town, Uasin Gishu County, in the western part of Kenya. It is actually the second largest National Teaching and Referral Hospital (level 6 Public Hospital) in Kenya with a bed capacity of 1,020 patients (MTRH Central Records, 2021), an average number of 1300 of inpatients at any time and about 1500 out patients per day.

The Hospital serves residents of Western Kenya Region (representing at least 23 Counties), parts of Eastern Uganda and Southern Sudan with a catchment population of approximately twenty-four (24) million. MTRH is also the Teaching Hospital for Moi University College of Health Sciences that trains both Undergraduate Medical Students and several Masters in Medicine Specialist programs with over 240 postgraduate students (Registrars) distributed across several programs. Several other training institutions for diploma and degree courses utilize MTRH in their training programs.

MTRH serves as a teaching facility for several anaesthesia programs like Higher National Diploma (HND) in anaesthesia; Master in Medicine (M.MED) in Anaesthesia and Critical Care; and College of Anesthesiologists of East, Central and Southern Africa (CANECISA) programs. It also offers elective attachment for Anaesthesia students from other universities.

There are three operating theatres in MTRH and each theatre has several operating tables with the main theatre having six operating rooms besides a dedicated Maternity theatre which has two operating rooms. The rest of the operating theatres have two

operating tables each making a total of twelve operating rooms. The anaesthesia providers include seven nurse Anaesthetists, thirty-one HND Anaesthetists, nine Anesthesiologists and also students on training. Elective cases run on weekdays while emergency theatre cases are done every day, day and night with a dedicated theatre for general emergencies and another one to handle obstetric cases.

3.2 Study Design

A prospective observational study was done on patients who underwent spinal anaesthesia technique from July to December 2022 and recorded the occurrence or non-occurrence of PDPH. During the study, participants' time points were assigned at 24hrs, 48hrs, 72hrs and 7days and assessed for the primary outcome which was occurrence of PDPH as per the International Headache Society (IHS) diagnostic criteria. We also assessed the treatment modalities administered (both by self and by the clinicians) and measured the treatment outcomes which were documented in terms of resolution of headache or persistence.

3.3 Target population

The target population included all patients undergoing both elective and emergency surgeries at MTRH.

3.4 Study Population

The study population was all adult patients aged above 18 years undergoing various surgeries under spinal anaesthesia at MTRH.

3.5 Eligibility Criteria

3.5.1 Inclusion criteria

- All patients who underwent surgery under spinal anaesthesia.
- Patients who met ASA I-III criteria as per the appendix on ASA classification.

3.5.2 Exclusion criteria

- Patients who had history of migraine or chronic headaches at the time of recruitment.
- Patients aged less than 18 years of age.

3.6 Sample Size Determination

In order to determine the minimum sample size needed to answer the research question, a sample size was determined using Cochran's formula (Cochran, 1963) for determination of sample size as follows;

$$n = \frac{Z_{\alpha/2}^2 p (1 - p)}{d^2}$$

Where:

n= was the sample size desired (when population is greater than 10,000)

p= was the (estimated) proportion of the population which has the attribute in question. 20% was used (E. Gisore et al., 2010)

q=1 – p.

d= was the desired level of precision (i.e. the margin of error), which corresponded to 5%

Z= was the standard normal deviation usually set at 1.96 (corresponds to 95% confidence interval)

Therefore, deriving the above formula we get.

$$n = \frac{1.96^2 \times 0.2 \times 0.8}{0.05^2} = 246 \text{ patients}$$

$$n = [(1.96)^2 \times 0.2 \times 0.8] \div (0.05)^2$$

$$n = (0.615) \div (0.0025)$$

$$n = 246$$

From a records search in the MTRH Central records registry, in the year 2019, out of the total 12,023 surgeries done, 3068 were done under spinal anaesthesia translating to about 1022 over a 4-month period. Therefore, assuming a population size of 1022 a finite population correction was conducted to get the final sample size as follows;

$$n1 = \frac{n}{1 + \frac{n}{N}}$$

Where;

N1= was the desired sample size

n= the initial sample size calculated (246)

N= total population target (total number of patients undergoing spinal anaesthesia in 4 months period) in this case 1022.

Therefore;

$$n1 = \frac{246}{1 + \frac{246}{1022}} = 198 \text{ patients}$$

3.5. Sampling Technique

A systematic sampling technique was used in this study. At commencement of the study, the patients were stratified based on the specialties and put into three groups i.e. Obstetrics and gynecology, Orthopedics and Others (General surgery, Plastic surgery and Urology).

A random starting point was selected for each group and then a systematic sampling technique was used subsequently for all the specialties with a sampling interval of 5 i.e. $1022/198=5$, until the sample size was achieved. Therefore, recruitment was done on every 5th subject in every group who gave consent from the target population.

3.7 Data Collection Methods

During data collection, all patients who had successfully undergone surgery under spinal anaesthesia were identified from theatre records of every operating room across all MTRH theatres. This was done daily after the surgical procedures were completed. In this study, standardization was ensured by use of same size spinal needle across all the specialties whereby size 25 quinckes needle was used. Sampling was then done and the study participants were followed in their wards where informed consent was obtained before recruitment into the study. The study participants were then followed at specific time points. An interviewer administered questionnaire was the main tool used for data collection I n this study. In addition, all the medical files for patients who developed new onset headaches were checked for diagnosis and also confirmed and documented the prescribed medications from the treatment sheets of those patients.

Two trained research assistants assisted with identification of potential study participants, recruitment and also data collection. Those who gave consent were followed at specific participants' time points i.e. 24hrs, 48hrs, 72hrs, 7 days and finally after 30days and documented occurrence or non-occurrence of new headache. During the follow-up period, phone contacts of the study participants and those of their close relatives were taken and therefore follow up was physically in the various wards immediately after surgery and then through phone calls upon discharge from the hospital. Any new onset headache was documented and subjected to the diagnostic tool as per the International Headache Society. Occurrence of the primary outcome which was development of PDPH together with the characteristics of the headaches was then documented. Data collection procedure is as per the table below.

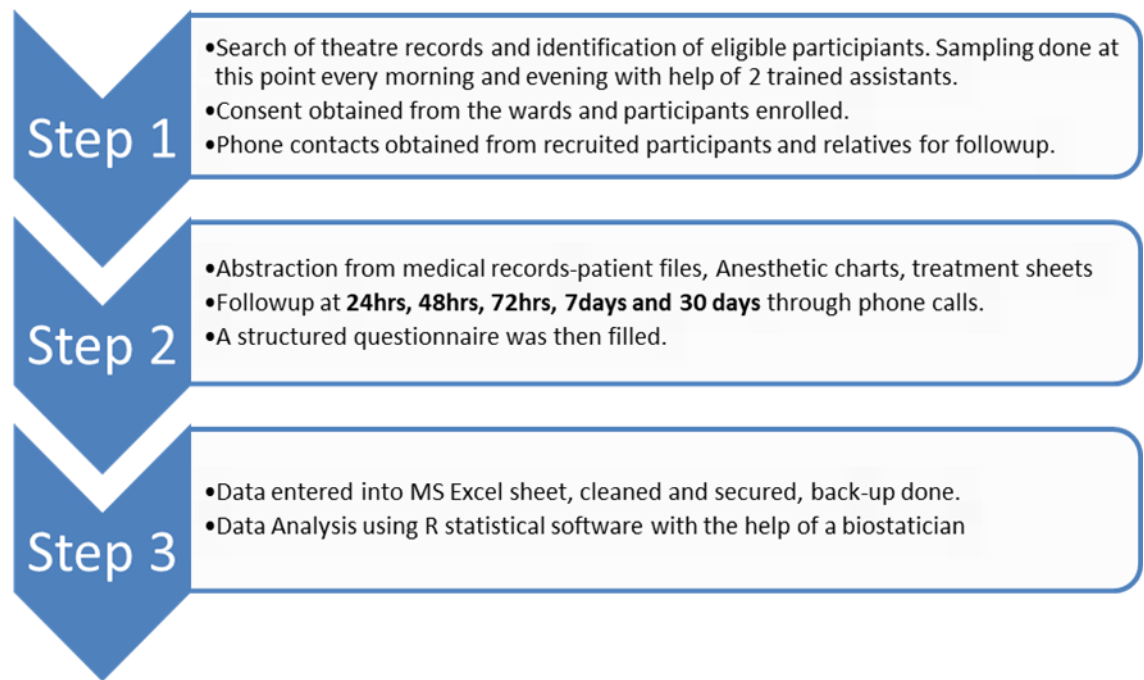


Figure 3: Data collection methods

Thereafter after identification of the primary outcome, several aspects like onset, severity, treatment options administered and the treatment outcomes of Post Dural Puncture Headache were then investigated. The onset of the headache was classified based on duration from the time of spinal Anesthesia, severity was described as mild, moderate and severe while the treatment outcomes were classified into; complete relief, incomplete relief of symptoms and failure as per (Annex 3) below. The severity of the headaches was then described using the Visual Analogue Scale as per (annex 4)

Data collection was done by the primary investigator with the help of trained assistants through investigator administered questionnaires. The data collected included demographic data, ASA classification, type of surgery and the surgical specialty, time of surgery and number of dural puncture attempts done before success of the spinal anaesthesia. During this study, some data was extracted from the participants' personal files including both the Anesthetic charts and the operation notes. In addition, the weights and heights of participants and calculated the body mass index (BMI) of the study participants. Lastly, the rest of the information was

directly extracted from the study participants through direct interviews. Data was collected on the stipulated time intervals, entered on excel sheets and the data forms were updated on a weekly basis.

Out of a target population of 5436, 1612 underwent surgery under spinal Anesthesia of which 198 study participants were followed up. Eight participants dropped out due to loss of follow-up and a total of 190 participants completed the study of which 45 of them developed PDPH after subjecting the symptoms to the diagnostic tool.

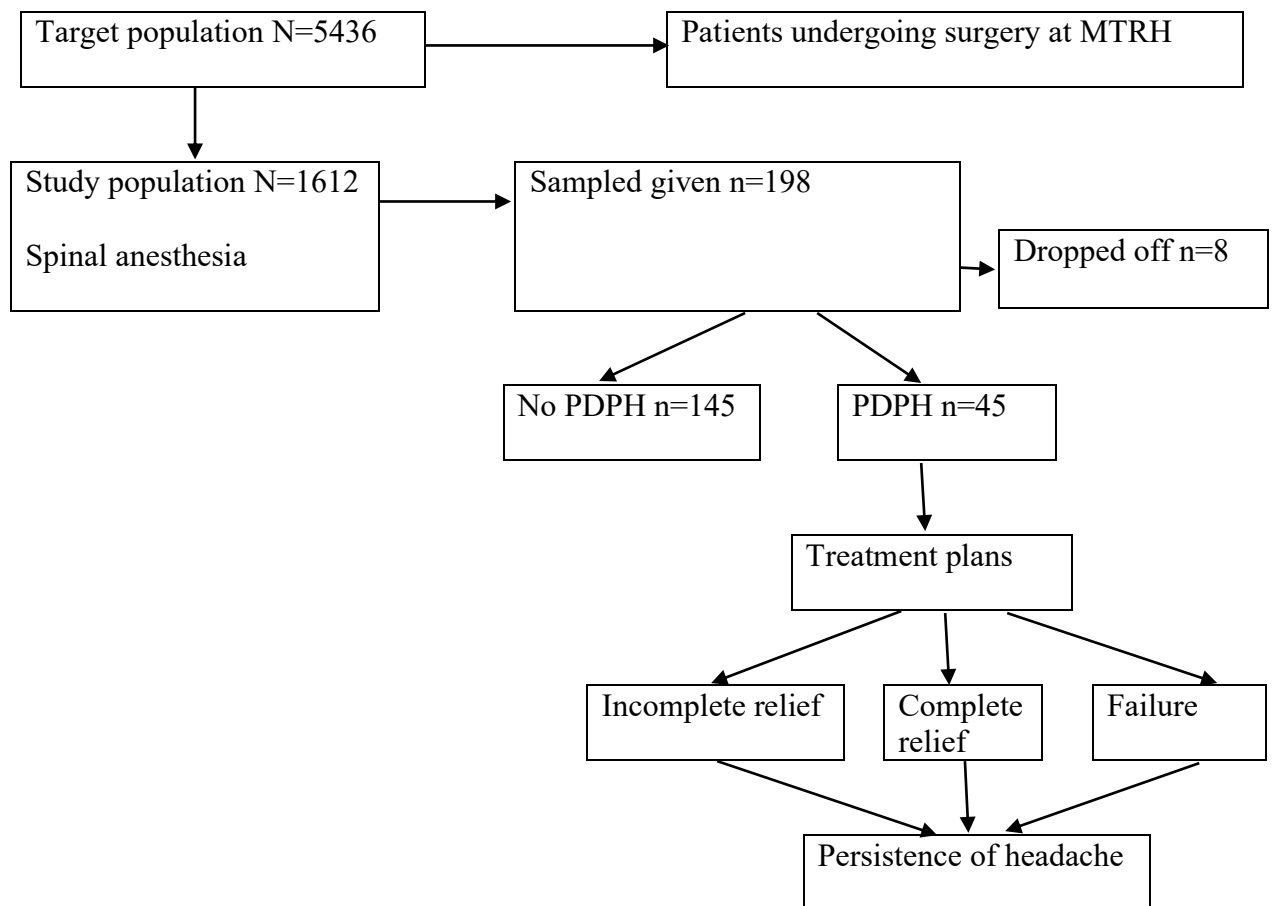


figure 4: study recruitment schema

3.8 Data management

The relevant data was collected from the study subjects through questionnaires and entered into database through Microsoft Excel. To ensure data security, authenticity and also confidentiality, the database was secured with a password at all times and only the principal investigator could access the information. In addition, no personally identifying information such as patient names and national identification numbers of the study subjects was put on any of the data forms. Also, back up of data on an external hard disk was ensured to cushion against data losses and the primary investigator retained the right to custody at all times.

All the questionnaires were kept in a safe cabinet under a lock and the principal investigator retained the keys at all the times. After data entry into the database, all the records were verified and any missing data and anomalies were corrected by the principal investigator. The principal investigator ensured that questionnaires and data forms were kept safely after the research was completed and those records would be kept for a period of five years before disposal.

3.9 Data analysis

Demographic variables were presented using tables. Firstly, the data was subjected to tests of normality and measures of central tendency such as mean and median with the respective measures of variation (standard deviation and interquartile ranges) were used to summarize continuous variables while categorical variables were summarized using frequencies and percentages as highlighted in the table below. Chi square test was used to assess association between categorical variables while ttest was used to compare means between two groups. All analysis were carried out at 0.05 level of significance.

Table 1: Data analysis

Objective	Dependent Variable	Independent Variable	Test
Incidence	PDPH-Yes/No	None	Incidence
Proportion	Binary		Proportion and associated 95% CI
Associated Factors	PDPH-Yes/No	Age, BMI-Continuous	Bivariate: T-test for continuous
	Binary	Sex, Time of surgery, type of surgery-Categorical	Chi square test/Fishers exact test of association for Categorical data.
Treatment outcome	Outcome	None	Proportions and associated 95% CI for categorical outcomes
			Means and associated 95% CI for continuous outcomes

To assess the relationship between patient and clinical factors with development of PDPH, bivariate analysis using T test for continuous and Chi square test for categorical variables was used. The results were then presented using tables and graphs. For treatment outcomes, proportions were used for categorical outcomes while means were used for continuous variables. Data analysis was done using the R software for statistical Computing version 4.1.3.

3.10 Measures

3.10.1 Dependent variables

The dependent variables for this study were the primary outcomes; development of PDPH or non-occurrence of PDPH. The tool used for assessment of occurrence of PDPH was the International headache Society (IHS) criteria for diagnosis. The other outcomes that were measured in this study were the treatment outcomes which were

defined as; (I) Failure, (II) Partial relief and (III) Complete relief of symptoms/Success. Treatment failure in this case was defined as severe headaches despite administration of treatments/Analgesics, with interference of activity; partial relief on the other hand was defined as mild headaches and patient able to perform daily activities while complete relief was resolution of all the symptoms after administration of the interventions.

The interventions included both medical and non-medical modalities administered by the clinicians as prescriptions or individually by the patients. In this study, the protocol did not allow the principal investigator to initiate and administer the treatments or review the interventions which had been instituted.

3.10.2 Independent Variables

The independent variables in this study included specific factors likely to influence the outcome i.e. Development or non-occurrence of PDPH. The influence on the outcome by demographic characteristics such as age, sex and BMI were examined. Also, other surgery related factors like time of the surgery, type of surgery, duration of surgery and the specialty were also investigated to determine whether they had any influence on the development of PDPH amongst the participants.

3.11 Ethical Considerations

Ethical approval required to conduct this study was sought from the Institutional Research and Ethics Committee (IREC) of the Moi University. In addition, further permission was obtained from the Chief Executive Officer (CEO) of MTRH before the commencement of data collection.

The study was then conducted with respect for confidentiality and also with respect for human dignity. We ensured that no harm of any kind was inflicted on the study

subjects and no invasive procedures were performed altogether in this study. In addition, we ensured that before the informed consent was obtained, the explanations were provided by the primary investigator or the study assistants in a language that they could understand, and patients' informed consent was sought before inclusion into the study. At all times, data remained anonymous in the data registries by assigning codes, and therefore no personal names were put in the data registries.

3.12 Expected Benefits

No financial or direct benefits were extended to the study subjects during or after the study. This study will help in development of awareness about PDPH and its risk factors. The results of this study will also help as a guideline in developing protocols to aid in prevention and proper management of PDPH. This study is therefore expected to fill in the knowledge gap and aid the clinicians to prevent the development of PDPH and also to manage their patients better.

3.13 Study Limitations

There was no standardization of the premedication before surgery. For instance, some patients may have received preoperative analgesics, anxiolytics or intravenous fluids before surgery while others may not have gotten the same medications. The standard MTRH pre-anaesthetic protocol was adhered to although there could have been variations.

During the study period, gauge 25 quinckes needle was the commonly used spinal needle but occasionally we had G22 quinckes needle. The size of the spinal needle used was documented on the anesthetic charts during the study period but since the primary investigator was not the one doing the procedure, improper documentation cannot have been ruled out.

Also, there were different anaesthesia providers who administered the spinal anaesthesia including students and qualified anaesthetists and this could have significantly affected the uniformity of the spinal technique in this study.

Other factors that may have arisen include documentation of the height, weight, body mass index and number of attempts during the procedure since they were not traditionally part of the mandatory data required preoperatively. During data collection, different measurement scales from the various wards were used to take the weights and heights of the patients and this may not have been standardized and therefore errors could have occurred. Also, we could not take the vertical heights in some patients and therefore we had to measure the horizontal heights.

CHAPTER FOUR

4.0. RESULTS AND FINDINGS OF THE STUDY

4.1. Introduction

This chapter covers the findings of the study and captures the demographic characteristics of the study subjects, patient characteristics and also procedure related characteristics as per the study objectives. The results are based on 198 patients who underwent both elective and emergency surgeries at MTRH during the study period. A total of 8 patients were lost to follow up and therefore 190 patients were analyzed to determine the incidence of PDPH. The data has been presented in form of tables, percentages and proportions.

4.1.1. Socio demographic characteristics

The age of the study participants ranged from 18-64 years with a mean age of 31.2 ± 9.9 . Females were 72.7% and Christians represented 98.5%, Muslims 0.5% and other religions 1%. 37.9% had attained High School education, 37.4% Elementary education, 20.75% College and 4.0% (Table 2). The data was normally distributed and therefore the means and respective Standard deviations were calculated.

Table 2: Demographic Characteristics

Variables	N=198 Frequency
Age	
Mean(SD)	31.2 (9.9)
Range	18 – 64
Sex	
Male	54 (27.3%)
Female	144 (72.7%)
Religion	
Christian	195 (98.5%)
Muslim	1 (0.5%)
Others	2 (1.0%)
Level of Education	
Elementary	74 (37.4%)
High School	75 (37.9%)
College	41 (20.7%)
University	8 (4.0%)

#SD Standard Deviation

4.1.2 Clinical characteristics of the patients

The BMI of the participants ranged from 16.4-47 with a mean of 27.5 ± 5.3 . Normal BMI accounted for 32.3%, obese 28.8% and Overweight 38.9%. Non-smokers were 92.9% and 84.3% did not take alcohol. Around 67.2% had no history of spinal anaesthesia. ASA I respondents were 56.1%, ASA II 39.4% and ASA III 4.5%. Emergency surgeries were 60.1% and the Length of surgery was <2 hours 86.4%, 2-4 hours 13.1% and >4 hours 0.5%. (Table 3 below).

Table 3: Clinical Characteristics

Variables	N=198 Frequency
BMI	
Mean(SD)	27.5 (5.3)
Range	16.4 – 47
BMI	
Normal	64 (32.3%)
Overweight	77 (38.9%)
Obese	57 (28.8%)
Smoking	
No	184 (92.9%)
Yes	14 (7.1%)
Alcohol Use	
No	167 (84.3%)
Yes	31 (15.7%)
History of Spinal	
No	133 (67.2%)
Yes	65 (32.8%)
History of PDPH	
No	178 (89.9%)
Yes	20 (10.1%)
ASA	
I	111 (56.1%)
II	78 (39.4%)
III	9 (4.5%)
Type of Surgery	
Elective Surgery	79 (39.9%)
Emergency Surgery	119 (60.1%)
Length of Surgery	
<2hrs	171 (86.4%)
2-4hrs	26 (13.1%)
>4hrs	1 (0.5%)
Specialty	
Obstetrics	122 (61.6%)
Orthopedics	56 (28.3%)
Urology	10 (5.1%)
General Surgery	8 (4.0%)
Others	2 (1.0%)
Time of Surgery	
Day	110 (55.8%)

Night	87 (44.2%)
No of Attempts	
1 Attempt	125 (63.1%)
2 or More Attempts	73 (36.9%)

#SD-Standard Deviation

4.1.3 Incidence of PDPH

This section looks at the hospital incidence of PDPH at MTRH. The section also highlights the characteristics of the headaches in terms of severity, time of onset and location of the headaches as reported by the study participants.

From the 198 study participants recruited, eight (8) of them were lost to follow- up and therefore the final analysis included 190 participants. Forty five (45) participants (23.7%) developed PDPH (Table 4)

In 56.8% of the cases, the headache was localized in the frontal region and 65.9% of the cases were reported within 24 hours after surgery. 29.5% were mild, 31.8% moderate and 38.6% were severe as per the VAS.

Table 4: PDPH incidence

Total	
N=198	
PDH	
Lost to follow-up	8
No	145 (76.3%)
Yes	45 (23.7%: 17.8-30.4)
Location	
Frontal	25 (56.8%)
Occipital	9 (20.5%)
Generalized	5 (11.4%)
Frontal + Occipital	4 (9.1%)
Temporal	1 (2.3%)
Time of onset	
Within 24 hours	29 (65.9%)
24-48hours	9 (20.5%)
48-72hours	5 (11.4%)
After 3 days	1 (2.3%)
Severity	
Mild	13 (29.5%)
Moderate	14 (31.8%)
Severe	17 (38.6%)

4.1.4 Associated factors for development of PDPH

In this study, the number of males who developed PDPH were (26.9%) as compared to the percentage of females who developed the condition (22.5%). We found that 30% of those who had prior history of spinal block developed PDPH while for those who didn't have prior history of spinal anaesthesia, only 20% developed PDPH. Also, PDPH developed in 36.7% of those who had used alcohol in the past while 21.3% of those who had never taken alcohol in their lifetime developed PDPH. The incidence of PDPH increased with ASA classification as follows; ASA I 21.7%, ASA II 26.3% and ASA III 25.0%.

Elective cases had an incidence of 30.7% while in Emergency cases, we had an incidence of 19.1%. The incidence per specialties were Orthopedics 30.2%, Obstetrics

and gynecology 22.2% and others 15.0%. The incidence of PDPH in surgeries which took less than 2 hours was 22.6% as compared to surgeries which took more than 2 hours 30.8%. Day surgeries had an incidence of 27.4% while night surgeries 18.1%. Those who had more than 1 prick had an incidence of 32.4% compared to 18.3% in those who had successful lumbar puncture on the first attempt (Table 5)

Table 5: Associated factors for development of PDPH

	No	Yes		N=190
	N=145	N=45	Test statistics	p-value
Age	31.3 (10.3)	31.2 (8.3)	ttest	0.962 ³
Sex			Chi square	0.519 ¹
Male	38 (73.1%)	14 (26.9%)		
Female	107 (77.5%)	31 (22.5%)		
BMI	27.5 (5.4)	27.9 (4.9)	ttest	0.683 ³
Smoking			Fisher's exact	0.736 ²
No	134 (75.7%)	43 (24.3%)		
Yes	11 (84.6%)	2 (15.4%)		
Alcohol Use			Chi Square	0.068 ¹
No	126 (78.8%)	34 (21.3%)		
Yes	19 (63.3%)	11 (36.7%)		
History of Spinal			Chi Square	0.164 ¹
No	103 (79.2%)	27 (20.8%)		
Yes	42 (70.0%)	18 (30.0%)		
ASA			Fisher's exact	0.722 ²
I	83 (78.3%)	23 (21.7%)		
II	56 (73.7%)	20 (26.3%)		
III	6 (75.0%)	2 (25.0%)		
Type of Surgery			Chi Square	0.068 ¹
Elective Surgery	52 (69.3%)	23 (30.7%)		
Emergency Surgery	93 (80.9%)	22 (19.1%)		
Length of surgery			Chi Square	0.360 ¹
<2hrs	127 (77.4%)	37 (22.6%)		
>=2hrs	18 (69.2%)	8 (30.8%)		
Specialty			Fisher's exact	0.374 ²
Obstetric	91 (77.8%)	26 (22.2%)		
Orthopedics	37 (69.8%)	16 (30.2%)		
Others	17 (85.0%)	3 (15.0%)		
Time of Surgery			Chi Square	0.134 ¹
Day	77 (72.6%)	29 (27.4%)		
Night	68 (81.9%)	15 (18.1%)		
No of Attempts			Chi Square	0.029 ¹
1 Attempt	97 (81.5%)	22 (18.5%)		
2 or More Attempts	48 (67.6%)	23 (32.4%)		

Key:

¹ Chi Square test

² Fisher's Exact test

³ ttest

4.1.5 Management of PDPH

We noted that there was no definite diagnosis of PDPH. There was also no specific treatment offered for those who developed PDPH.

From patient files search, there was no specific investigations done to aid in diagnosis or to rule out other causes of headaches. We therefore recorded the self-care measures, over the counter analgesics and also prescribed medications by the attending doctors when in the hospital and also after discharge.

Around 81.8% reported need for analgesics to relief the headache. Among the treatment options prescribed included NSAIDS 19 (43.2%), NSAIDS + Opioids 11 (25.0%), Paracetamol + Opioids 3 (6.8%), Paracetamol + NSAIDS 2 (4.5%), NSAIDS + Hyoscine 1 (2.3%), Paracetamol alone 1 (2.3%), Paracetamol + NSAIDS + Opioids 3 (6.8%) and those who had no analgesic prescription at all were 4 (9.1%). Majority of the patients with PDPH did not take any analgesics 20 (45.5%) while majority of those who took analgesics opted for Paracetamol alone 18 (40.9%) followed by NSAIDS 3 (6.8%) as shown in table 6.

Table 6: Management of PDPH

Self-measures	N=44
Rest/Fluids/Caffeine	12 (27.3%)
Rest/Fluids	11 (25.0%)
Rest	9 (20.5%)
Caffeine	4 (9.1%)
Rest/Caffeine	3 (6.8%)
Fluids	2 (4.5%)
Fluids/Caffeine	1 (2.3%)
Cold water Sponging	1 (2.3%)
None	1 (2.3%)
Need for analgesics	
No	8 (18.2%)
Yes	36 (81.8%)
Analgesic options taken	
None	20 (45.5%)
Paracetamol	17 (38.6%)
NSAIDS	3 (6.8%)
Paracetamol + NSAIDS	2 (4.5%)
Topical	1 (2.3%)
Others	1 (2.3%)
Drugs Prescribed	
NSAIDS	19 (43.2%)
NSAIDS + Opioids	11 (25.0%)
Paracetamol + Opioids	3 (6.8%)
Paracetamol + NSAIDS	2 (4.5%)
NSAIDS + Hyoscine	1 (2.3%)
Paracetamol	1 (2.3%)
Paracetamol + NSAIDS + Opioids	3 (6.8%)
None	4 (9.1%)

4.1.6 Assessment of the treatment outcomes for PDPH

The outcomes measures in this study were; 1. Failure-which meant that there was persistence of the headache without any relief of the symptoms, 2. Incomplete relief-whereby there was relief of the symptoms to some extent and the patients were able to resume their duties, 3. Complete relief-This is whereby there was complete resolution of the symptoms after the interventions/medications were given.

We noted that 29 of the positive cases (65.9%) had incomplete relief of the headaches while 6 of them (13.6%) had failure. At the same time, 20% had complete resolution of the headache immediately after the treatments as shown in the table below. While most symptoms resolved within seven (7) days (25.0%), around 22.7% of patients had symptoms which persisted for more than 1 week (Table 7)

Table 7: Treatment outcomes

	Total N=44
Outcomes	
Failure	6 (13.6%)
Incomplete relief	29 (65.9%)
Complete relief	9 (20.5%)
Resolutions of headaches	
Within 24 hours	5 (11.4%)
24-48hours	4 (9.1%)
48-72hours	11 (25.0%)
After 3 days	3 (6.8%)
Within 7 days	11 (25.0%)
Persistence for more than one week	10 (22.7%)

Table 8: Severity of headaches and analgesic prescribed

	Mild n=13	Moderate n=14	Severe n=17	N=44
Drugs Prescribed				
NSAIDS	3 (15.8%)	6 (31.6%)	10 (52.6%)	43.2%
NSAIDS + Opioids	6 (54.5%)	2 (18.2%)	3 (27.3%)	25.0%
Paracetamol + Opioids	1 (33.3%)	1 (33.3%)	1 (33.3%)	6.8%
Paracetamol + NSAIDS	1 (50.0%)	1 (50.0%)	0 (0.0%)	4.5%
NSAIDS + Hyoscine	0 (0.0%)	0 (0.0%)	1 (100.0%)	2.3%
Paracetamol	1 (100.0%)	0 (0.0%)	0 (0.0%)	2.3%
Paracetamol + NSAIDS + Opioids	1 (33.3%)	2 (66.7%)	0 (0.0%)	6.8%
None	0 (0.0%)	2 (50.0%)	2 (50.0%)	9.1%

The severity of headache varied depending on the analgesics prescribed. 52.6% of those who were prescribed NSAIDS alone experienced severe headaches

CHAPTER FIVE

5.0 DISCUSSIONS

5.1 Introduction to the chapter

Our objectives in this study were to investigate the incidence of Post Dural Puncture Headache, the associated factors for development of PDPH, management and treatment outcomes of the condition in patients undergoing spinal Anesthesia at MTRH.

A prospective cross-sectional study was conducted on patients undergoing spinal Anesthesia on various surgical specialties in MTRH, Eldoret which is a teaching and referral hospital located in the Western region of Kenya.

Systematic sampling technique was used and a total of 198 study subjects were recruited from the target population. Majority of the study participants were relatively young as demonstrated by the mean age of 31.2 years ($SD \pm 9.9$). This compares to a study done in Nigeria (Nuhu et al., 2017) whereby their mean age was 30.98 ± 6.3 years. Young age has consistently been documented as a risk factor for development of PDPH from previous studies. Majority of the study participants were females (72.7%) compared to males (27.3%) and this could have been because we included obstetric patients in this study. It is not clear whether this could have been due to differences in health seeking behaviors between males and females.

The majority of the participants were Christians at (98.5%) as compared to other denominations because the communities living in surrounding geographical region are predominantly Christians.

In addition, the highest number of participants had attained High school level of education (37.9%). This could have been because majority of the patients were young

participants, who were likely to have attained higher level of education as compared to older populations. Indeed, the results could have been different had we studied predominantly the older population in our setting.

The mean BMI of the participants in this study was (27.5) with $SD \pm 5.3$. We noted that majority of the participants were overweight (38.9%) as compared to those who had normal BMI (32.3%). This compares with results from a Kenyan study (Mkuu, Epnere, & Chowdhury, 2018) which found out that a higher proportion of Kenyan women are either overweight or obese.

Besides, the least proportion of the study participants had a prior history of PDPH (10.1%) and this could have been as a result of the smaller number of study participants who had undergone spinal procedure previously (32.8%) as compared to those who were undergoing the procedure for the first time.

Physiological status of the study participants as shown by the ASA classification depicted that majority of the patients (56.1%) were ASA I patients who were generally healthy at the time of surgery. However, no evidence has been shown from previous studies on any association between the ASA physiological status of patients and development of PDPH.

We had more emergency surgeries in this study (60.1%) as compared to elective surgeries (39.9%) and this compares with a study done by (Ikol, Saula, Gisore, Mvungu, & Mwangi, 2019) at MTRH which showed that (60.2%) of the surgeries done at MTRH were emergency cases, though this was a study done in neonatal population. Going by this finding, it is therefore possible to conclude that most of the county referral hospitals are handling majority of the elective cases.

5.1.1 Patient Characteristics

The age range of the participants in the data set was 18 to 64 years old, with a mean age of 31.2 years with a standard deviation of ± 9.9 . Notably, the majority of participants (72.7%) were female. This is consistent with other research (C. Wu et al., 2016) and also a study by (Bajwa & Sharma, 2015) that showed a higher number of female patients in the studies. Coincidentally, those studies and other previous literature have indicated a higher incidence of certain medical conditions in females, such as post-dural puncture headache (PDPH).

Furthermore, 98.5% of participants self-identified as Christians, which may have an effect on cultural attitudes and customs surrounding healthcare. There is documented interplay between religious beliefs, cultural practices, health seeking behavior and outcomes as demonstrated by a study done in Nigeria (Adomah, 2023). In terms of levels of education, the distribution reveals that a considerable number of participants had completed high school (37.9%), with elementary school graduates coming in second at (37.4%). According to (Firdaus, Purnawa, & Widiyaningsih, 2023), people with higher education levels may have superior comprehension and communication skills regarding their healthcare, which could have an impact on health literacy and understanding of medical procedures.

In another similar study done in Ethiopia, the mean age was (29.44), (Lotfy Mohammed & El Shal, 2017) which is significantly lower than the mean age in the current study. This could have been because unlike in the current study where we included all surgical specialties, previous studies have looked at the incidence of PDPH in obstetric participants whereby the age is usually lower as compared to other specialties.

However, similar to (Bajwa & Sharma, 2015), a study by (van de Beek & Brouwer, 2018) showed a significantly higher mean age of (38.6) years and a higher percentage of female participants as compared to our study but those studies were not conducted in an African setting and therefore possibly the reason for the higher age bracket.

5.1.2 Clinical Characteristics of Patients

With a mean BMI of (27.5 ± 5.3) in this study, which was above the cut-off for normal BMI levels, a large proportion of the participants were either obese (28.8%) or overweight (38.9%), which contrasts with studies done in Kenya by (Pengpid & Peltzer, 2020) but compares with results from a study by (Mkuu et al., 2018) which showed that majority of Kenyan women are either overweight or obese.

In this study, most of the participants reported never having smoked previously (92.9%) and majority had never taken alcohol in their past (84.3%). We therefore noted that drinking alcohol and smoking were not common in our study population and this could be explained probably by the fact that majority of the participants were females and studies have shown less of these behavior in female population. However, it is also possible that this could have been affected by less reporting from the study participants.

Besides, previous studies have not shown evidence on association of those behaviors and development of PDPH. Nevertheless, it might be difficult to reach firm conclusions regarding how smoking and alcohol consumption affect the incidence of PDPH given the relatively low prevalence of these behaviors in our study population.

One important finding was that (32.8%) of participants reported having previously undergone spinal anesthesia for other surgical procedures in the past. Out of those,

(10.1%) of patients with a history of spinal anesthesia had experienced PDPH-like headaches as per the IHS diagnostic criteria on further inquiry.

This is consistent with other research showing that a history of spinal anesthesia exposure may increase the risk of PDPH (Nambooze, Samuel, Kiggundu, Kintu, & Nabukenya, 2019).

ASA I patients were (56.1%) and this represented the majority of participants. This implies that majority of the patients recruited in this study were of good physiological status and devoid of underlying comorbidities; ASA II and ASA III patients were (39.4%) and (4.5%) respectively.

5.1.3 Surgical Characteristics

Compared to elective procedures which were the minority (39.9%), emergency surgeries accounted for a higher proportion of procedures (60.1%). This compares with a study done by (Ikol et al., 2019) in the same setting. MTRH being a referral facility, we expect that more emergency cases to be done as compared to elective cases given the fact that elective cases are usually scheduled while emergency cases are usually done every day. The probability of developing PDPH may arguably be impacted by the urgency of the surgical procedure, probably due to elevated stress levels and modified physiological responses to stress though recent studies have shown conflicting results and therefore an area which requires more studies.

Moreover, over (86%) of the surgeries in the current study lasted less than two hours, which meant that the majority of procedures took relatively shorter durations. This could have been as a result on inclusion of obstetric cases which tend to take a relatively shorter duration as compared to other procedures like orthopedic, general surgery or urological cases.

The highest percentage of surgeries (61.6%) were performed in obstetrics and gynecology, followed by orthopedic cases at (28.3%). It is possible that comparing the incidence rates for the various specialties may be biased because of the lower numbers for some surgical specialties and therefore, looking at the overall incidence rate for all the study participants may be more reliable and informative.

Majority of the procedures were done at night during which we have less staff and therefore timely interventions, when needed, may not be as prompt as compared to during the day. As much as there is little direct evidence to connect the time of surgery to the incidence of PDPH, several factors like staffing levels, fatigue, and circadian rhythms may have an indirect impact on the success of surgery and the recovery of patients, though this is an area which requires more research.

The time of surgery and other related factors like fatigue may also determine the number of attempts before a successful lumbar puncture, several attempts before the success of spinal anaesthesia have been documented as a major factor in determining the occurrence of PDPH (Weji, Obsa, Melese, & Azeze, 2020). In this study, we noted that 36.9% of participants needed two or more attempts, which is significantly high. A similar study by (Tafesse & Melkamayew, 2018) showed similar results and as such, sufficient training in skills acquisition in spinal anesthesia procedures can minimize the risk of complications like PDPH by reducing the number of attempts before a successful lumbar puncture.

5.2 Incidence of PDPH

In this study, the overall incidence was 23.7% whereby 8 participants were lost to follow up and 45 out of 190 study participants experiencing mild, moderate and severe symptoms during the follow-up period. This result is consistent with earlier

studies conducted by (Namboozee et al., 2019) with a surprisingly similar incidence rate of 23.7% within the 7th day after the procedure.

The incidence of PDPH from this study was also within the range reported in other Kenyan studies for example, (Edna Gisore et al., 2010) revealed that when registrars performed a Caesarean section under spinal anesthesia, 27.5% of the women experienced PDPH, whereas 15.1% experienced PDPH if a consultant did the procedure.

Another recent study done in Thika Level 5 hospital (Nduku et al., 2023) showed an incidence of 24.5% which was similar to our findings. A study done in Nigeria on patients undergoing emergency and elective Caesarian section revealed a general prevalence of 22% (Nuhu et al., 2017) which they actually considered higher than what had been found in previous studies. Additionally, the results of our study show a significantly lower incidence as compared to an Indian study which showed an incidence of 41.25% (Monga, 2021)

Incidentally, the incidence rate from this study was much lower than findings in a study from Ethiopia (Ferede, Nigatu, Agegnehu, & Mustofa, 2021) which showed a 31.3% incidence rate. This could have been because in our study, we sampled participants from different specialties unlike the Ethiopian study where only obstetric patients were included. Female gender and obstetric cases have been reported as major risk factors for development of PDPH in previous studies.

The results of this study also show a significantly lower incidence rate compared to a study done in India in obstetric patients which showed an incidence of 41.25% though in this study, majority of the patients used bigger spinal needles (G20, G21, G22) as compared to those who used smaller spinal needles (Monga, 2021)

There could also be differences in the incidence of PDPH in developed world compared to non-developed world as shown in a study done in Netherlands (Duits et al., 2016) which showed that 19% of patients reported headaches following lumbar punctures, with only 9% of the participants showing classical symptoms of PDPH. This therefore implies that in centers with better resources, preventive strategies can be instituted to minimize the risk of PDPH development in patients undergoing spinal anaesthesia or lumbar puncture.

Incidentally, even in settings with adequate resources, the incidence of PDPH can be high as shown by results from a recent study in Spain by (Rodriguez-Camacho, Guirado-Ruiz, & Barrero-Hernández, 2023) which showed an incidence rate of 38.6% and therefore this is not a problem for non-developed world.

According to (Molina MB & Borraz P, 2016), the typical incidence of PDPH when using smaller needle sizes (G27) is actually 0%–14.5%, so the results of our study were significantly higher than the recommended. However, we did not do comparison of needle sizes and incidence rates in this study and therefore a future study would be beneficial since future studies in our setting comparing needle sizes and shapes will help evaluate the impact of procedural factors like the type and shape of spinal needle in development of PDPH so as to take those factors into account when designing protocols aimed at prevention of PDPH.

Post spinal puncture CSF leakage from a dural defect and subsequent intracranial hypotension are the causes of PDPH after spinal anaesthesia. These events can happen more frequently after spinal anesthesia or after a dural puncture using a cutting spinal or epidural needle when there is an inadvertent dural tear and subsequent leakage of CSF volume. Needle stick designs therefore is well known for having drastically

lowered the risk of PDPH to approximately 1% when spinal anesthesia is given using a pencil shaped spinal needle (Molina MB & Borraz P, 2016). It is therefore likely that the incidence would be much lower had pencil shaped spinal needles been used for administration of spinal anaesthesia.

The study's characterization of PDPH characteristics sheds important light on the nature of this frequent side effect after spinal anaesthesia and also helps to distinguish the condition from other migraine conditions as described by the International Headache Society (IHS). We realized that in this study most of the headaches were frontal in origin (56.8%), followed by occipital region headaches (20.5%). On the other hand, generalized headaches were the least reported by the study participants at (11.4%). These results support earlier studies by (Lotfy Mohammed & El Shal, 2017) who similarly noted a high frequency of headaches in the frontal-occipital region, pointing to a shared headache localization pattern among PDPH patients.

According to our study, majority of the headaches (65.9%) started within the first 24 hours following surgery, followed by a smaller percentage (20.5%) that started between 24 and 48 hours while the smallest percentage (11.4%) occurred between 48 and 72 hours after surgery. This early onset of symptoms is consistent with results from (Vallejo & Zakowski, 2022) who found that most patients (65%) experienced headaches within the first 24 hours following surgery. It is therefore apparent that much vigilance and surveillance is needed in the first 24 hours following administration of spinal anaesthesia especially in high risk groups to identify and manage those who develop the condition. It is possible that the differences in patient populations and surgical techniques between studies may be the cause of this disparity in onset times, as much as results point towards a similar trend.

Surprisingly in this study, we noted that most of the reported headaches were severe (38.6%), followed by moderate headaches (31.8%) and mild headaches were (29.5%) as per Visual Analogue Scales (VAS) and Numerical Rating scales (NRS) unlike documented in almost all the previous studies whereby the headaches have been reported to be mainly mild or moderate. However, cumulatively, mild to moderate cases combined amounted to 61.3% and therefore the results compare to those of (Khraise et al., 2017) who noted that the majority of their patients had mild to moderate headaches.

Additionally, (Pirbudak et al., 2019) noted that in their study most of the patients had mild to moderate headaches which were treated conservatively without the need of Epidural Blood Patch (EBP). Since most of our cases had severe headaches, the impact of this condition on the recovery and general well-being of our patients cannot be underestimated and resolutely underscores the importance of effective pain management techniques and strategies as well as preventive measures to mitigate against unnecessary suffering due to PDPH post-operatively.

5.3 Associated factors for development of PDPH

5.3.1 Age and gender

In this study, we found out that more Males (26.9%) than females actually developed PDPH as compared to females (22.5%), though this surprisingly contradicts earlier studies whereby females were found to be significantly more likely to develop the condition. In recent studies as demonstrated by (CELEP, MERMER, & ULUER, 2021) and (Al-Hashel, Rady, Massoud, & Ismail, 2022), female patients had three times odds of developing PDPH as compared to their male counterparts.

These observed discrepancies in the results may be explained by variations in the study populations, sample sizes, or methodologies used compared to our study. Most studies do generally agree that a lower age is linked to a higher risk of PDPH. As a confirmation of a similar trend, the results of this study show that the majority of patients developing PDPH were between the ages of 30-39 (29.9%), which was comparatively the younger population amongst our study participants. These study findings agree with the findings of (Al-Hashel et al., 2022), who reported a mean age of 28.3 years for development of PDPH.

The reason why age and gender has been implicated in development of PDPH is attributed to the differences in elasticity of the dural fibers due to the collagen and elastic fibers. Consequently, research results from multiple studies offer important new understandings of the demographic variables linked to the emergence of PDPH following spinal anesthesia and it is notable that young age and female gender have been documented as risk factors (Uppal et al., 2023) with a high level of evidence.

According to (Janssens et al., 2003), PDPH is a very rare condition in children, though it can still occur. However, there is conflicting data on this and therefore an

area of interest in future research. However, (DePizzo et al., 2020) noted that young adolescents aged between 12-19 years old had a threefold increase in the odds of developing PDPH as compared to the older counterparts.

Moreover, findings from (Mekete, Demelash, Almaw, & Seid, 2023) corroborate those findings that the incidence of PDPH declines with age, which is in line with the general notion that older people may differ in their dural elasticity and CSF dynamics. There are differences in the reported mean ages and gender distributions of PDPH patients, despite the fact that the studies generally concur on the trends pertaining to age and gender. As an example, (Celep et al., 2021) reported that, on average, male patients with PDPH were older than female patients, which is in contrast to the results of this study.

Variations in healthcare practices, sample selection criteria, or regional variations may all have an impact on these discrepancies. There are differences in the particular results even though there are recurring themes regarding how age and gender affect PDPH risk in the studies. Larger sample sizes and standardized techniques in future studies could help to clarify these differences and offer a more thorough grasp of the demographic variables affecting the incidence of PDPH.

Furthermore, fewer studies have been done in the pediatric population due to maybe consent issues, fewer regional anaesthesia being done in the young population or complexities of study designs and data collection in that population and therefore the argument that PDPH is very rare in children may not entirely be plausible. More research is still needed in this area despite the previous studies that have already been conducted.

5.3.2 BMI of the study participants and development of PDPH.

Due to anatomical factors and physiological changes, higher weight and BMI is usually associated with more muscle tissues at the back and therefore the spinal technique can be more challenging as compared to people with less tissue bulk.

The results of our study showed that participants with normal BMI measurements had a lower incidence of PDPH (25.4%) as compared to those in the obese category (26.8%), though the difference was not statistically significant.

The results of this study contrast with (Rodriguez-Camacho et al., 2023) who found out that participants with low BMI have higher incidence of PDPH. On the other hand, it was interesting to note that only 20% of those who were overweight developed PDPH. The findings of this study therefore contrasts with previous studies because overweight and obesity have frequently been postulated to present an increased risk to the condition. However, (Beyaz et al., 2021) found out that BMI values did not affect development of PDPH in the elective Cesarean section patients.

In this study, there could also have been other confounding factors like different specialties and qualifications of those who administered the spinal anaesthesia. Besides, a study on the BMI of patients and the number of pricks before a successful spinal anaesthesia in our local setting could help explain this phenomenon.

At the same time, one would argue that anatomical variations or physiological alterations linked to obesity may be one of the reasons for the increased incidence of PDPH among the obese patients as compared to the normal BMI patients.

Furthermore, comorbidities such as Diabetes Mellitus and also other Non-communicable diseases (NCDs) like Hypertension are more common in obese people,

which could be one of the confounding factors especially in cases where those lifestyle diseases are not diagnosed. (Huguet et al., 2021) noted that the rate of undiagnosed hypertension can be as high as (37.3%). On the other hand, the overweight group's lower incidence of PDPH raises controversies about possible protective factors or physiological variations specific to this population. It is possible that individuals classified as overweight might possess distinct adipose tissue distribution patterns or other metabolic traits that attenuate the risk of developing PDPH. However, more research is required to investigate these possible mechanisms and comprehend the underlying causes of the observed correlations between PDPH incidence and BMI.

Moreover, although from different angles, several research papers corroborate the link between BMI and PDPH risk. For instance, (Mekete et al., 2023) noted that obese patients had a significantly higher risk of developing PDPH than non-obese patients. Conversely, (Droby et al., 2020) highlighted the influence of BMI on PDPH incidence by reporting a markedly increased risk of developing PDPH in patients with BMI values between 25 and 29.9 (Overweight patients). These contradictory results highlight the nuanced nature of the relationship between PDPH risk and BMI and may be partly due to study methodologies applied in previous research.

Variations in intra-abdominal pressures linked to elevated body mass index (BMI) have been suggested as potential mechanisms in the literature, which may somehow lead to more CSF leakage in the case of a dural tear and could also impact the sealing of dural tears created during lumbar punctures. To completely comprehend the underlying mechanisms and resolve the disparities seen across the studies, more research is necessary.

5.3.3 Smoking and Development of PDPH

The results of a smoker's past smoking and the onset of PDPH provide interesting information about how smoking habits may affect the chance of developing PDPH after spinal anesthesia. In contrast to smokers who had a lower incidence of PDPH (15.4%), non-smokers had a higher incidence of PDPH (24.3%), although the difference was not statistically significant ($p = 0.47$). However, we did not look at the amount and duration of smoking in our participants as well as other forms of tobacco use so as to make strong conclusions. This like in previous literature raises concerns as to whether smoking is protective against PDPH.

In fact, for some time now, data has been consistent with smokers having lesser incidence of PDPH. A recent paper by (Mekete et al., 2023) found that non-smokers had a significantly higher risk of developing PDPH than smokers. The reason for this is not well known, though, (Uppal et al., 2023) hypothesized that the vasoconstrictive effects of nicotine could have an impact on the development of PDPH. This therefore reinforces the common old dogma that PDPH is less common in smokers than in non-smokers.

Other old studies also showed a similar trend, (Chapman & Wu, 2015) noted that the incidence of PDPH was significantly lower in smokers (13.7% vs. 34.1%, respectively) than in non-smokers despite excluding those who gave up smoking from their analysis. One of the emphasis and strong explanatory factor is that tobacco use, which contains nicotine through its stimulatory activity together with vasoconstrictive activity in the CNS can mask pain and therefore lead to lesser incidence and severity of PDPH. The inconsistency between the results of the current study and earlier studies highlights how complicated the connection is between smoking and the

development of PDPH, considering that other forms of nicotine use besides smoking have not been well studied.

While some research, like the current study, point to smoking's potential protection against PDPH, other studies have produced contradicting findings. These discrepancies may be explained by variations in the study populations, in the methodologies used, or by the impact of confounding variables that were not taken into consideration during the analyses.

5.3.4 History of Spinal Anaesthesia and Development of PDPH

The results of this study showed that people with a history of spinal anesthesia had a higher incidence of PDPH (30%) as compared to those without a prior history (20%). Even though the difference did not reach statistical significance ($p = 0.16$), it does point to a trend that merits more research.

This is consistent with findings from (Nduku et al., 2023), who found that people who had previously experienced PDPH were 2-3 times more likely to experience another episode of PDPH. The reasons for recurrence of PDPH after a previous episode are not well known and therefore is an area that requires more research. This also begs the question whether there could be other inherent genetic factors that may increase the chances of developing PDPH, such that once someone has had the condition, there is a greater preponderance to develop it again in the future.

Also, another plausible explanation would be that after repeated lumbar punctures, the dural fibers on the areas which have been cut can become weak and more susceptible to subsequent CSF leakage after repeated episodes of spinal anaesthesia technique.

While this current study finds no statistically significant association, other studies point to a higher risk of recurrence in people with a prior history of PDPH. There

exist several plausible explanations for these discrepancies, such as variations in the study populations, methodologies or other confounding variables.

5.3.5 History of alcohol use and development of PDPH

Those who have previously used alcohol were more likely to have PDPH than those who had never used alcohol. In particular, only 21.3% of participants who had never used alcohol developed PDPH, compared to 36.7% of those who had a history of alcohol consumption. Even though there was no statistically significant difference in the incidence of PDPH between the two groups ($p = 0.068$), this trend points to a possible relationship that merits more investigation. Indeed, there is no substantive previous data that shows the relationship between alcohol consumption and the development of PDPH. However, the findings were not conclusive and therefore more research is needed.

According to HIS, there is a classification of Alcohol induced headaches meaning that alcohol by itself can predispose to development of headaches. Therefore, those who have prior history of alcohol use could possibly report higher incidence of headaches after spinal anaesthesia.

5.3.6 ASA classification and development of PDPH

The results pertaining to the correlation between the categorization system of the American Society of Anesthesiologists (ASA) and the risks of developing PDPH offer significant understanding into the possible impact of patients' physiological condition on the likelihood of experiencing the condition. Nonetheless, there exist significant disparities in the findings among various investigations. According to the results of this study, the ASA II class had the largest percentage of individuals who acquired PDPH (26.3%), followed by ASA III (25%), and ASA I (21.7%). Although a trend seems to indicate that patients with higher ASA classifications have a higher

incidence of PDPH, the difference was not statistically significant ($p = 0.77$). This therefore leads to the unconfirmed conclusion that patients with better physiological status (ASA 1) have lesser chances of developing PDPH as compared to those who have other comorbidities.

This is consistent with the results of (Aniceto et al., 2023) who found that while the difference was not statistically significant, ASA II and ASA III patients had an incidence of (26.9%) and (8.3%) respectively which were much greater proportions of PDPH as compared to ASA I (9.1%). Also, in a similar study by (Nduku et al., 2023), similar results were noted though all the patients in this investigation were classified as either ASA II or ASA III, indicating a possibly higher risk group than that of our study.

Contrary to this, investigations by (Weji et al., 2020) and (Kassa, 2015) mostly included ASA class I patients, which might have had an impact on the incidence of PDPH but despite all that, they noted that the incidence was still high (28.7%) and 38.8% respectively. This shows that lower ASA classifications do not necessary modify the risk of developing PDPH.

While this study and some other previous literature do imply that individuals with higher ASA classifications have a higher prevalence of PDPH, some other studies show contradictory findings or find no statistically significant relationship. These differences may be due to differences in patient demographics, different study approaches or the impact of confounding variables that were not taken into consideration throughout the studies. Hence, need for more research which specifically looks at ASA groups and risk of PDPH. The reason why higher ASA

groups have a higher risk of developing PDPH is not well known but could be associated with the presence of other comorbidities like undiagnosed migraines.

5.3.7 Type of Surgery and Development of PDPH

Interesting insights into potential differences in risk between both surgery kinds can be gained from comparing the incidence of PDPH between elective and emergency procedures. According to the current study, elective operations had the highest incidence of PDPH (30.7%), whereas emergency procedures had the lowest prevalence (19.1%). Consequently, this can be explained by the possibility that in emergency surgeries, students undergoing training may not be given much opportunity to do the spinal blocks due to urgency nature of the surgeries, though this is inconclusive and other factors may come to play. There is however no previous data to support our findings.

PDPH was more common in orthopedic procedures (30.2%) than in other surgeries like obstetrics and gynecology (22.2%) and other disciplines (15.0%). The reason for this observation is not clear and therefore more research is needed. However, this could have been due to the relatively young age (mean age 31.2) in our study participants of which young age is one of the known risk factors. The trends show possible different patterns worth looking at going into the future, even if the differences were not statistically significant, $p=0.068$ for kind of surgery (elective vs. emergency) and $p=0.33$ for specialization. Previously, there has been a highly held dogma that PDPH is more common in women especially obstetric patients because of young age, repeated lumbar punctures and also effects of estrogen on cerebral vasodilatation.

On the contrary, (Aniceto et al., 2023) observed differing percentages of PDPH incidence in various surgical specialties, with the greatest percentage (40%), among gynecological cases, followed by orthopedic (17.9%) and general surgery (17.8%) while the incidence of PDPH was lowest (8.3%) in cases related to urology. Therefore, the results of the current study contradict these previous findings, especially with regard to the higher incidence of PDPH in orthopedic procedures when compared to obstetrics and gynecology.

The inconsistent results from several research demonstrate the intricate interactions among variables affecting the prevalence of PDPH in various surgical contexts. The disparities in patient populations, procedural procedures, anesthetic regimens, or postoperative care practices could be reasons for the variances in PDPH incidence between elective and emergency surgeries, or among various surgical specialties.

5.3.8 Duration of Surgery and Development of PDPH

An examination of how long surgery takes in connection to the occurrence of PDPH offers important insights into possible risk variables related to the time taken for the procedure to be completed. Though there is paucity of data on how the duration of the procedure is related to the development of PDPH, this study shows that the incidence of PDPH was 22.6% for procedures under two hours and 30.8% for surgeries that took over two hours, however, there was no statistically significant difference in the incidence of PDPH between the two groups ($p = 0.36$). These results point to a possible trend of longer procedures having a greater incidence of PDPH, which can be argued to be related to more time in the supine position during surgery which can lead to increased CSF leakage in the case whereby there is a dural tear.

However, other factors might potentially influence the risk of PDPH other than just the duration of surgery. Independent of the length of the surgery, variables such as patient characteristics, anesthetic methods, surgical complexity, and postoperative care guidelines may all influence the risk of PDPH. Shorter procedures may nevertheless be risky based on a variety of case-specific factors, even if longer surgeries could require prolonged anesthetic exposure and manipulation of spinal systems.

According to previous studies, there has not been any established relationship between the length of surgery and development of PDPH though there are no known relationship this far, therefore more research is needed to attempt answering those questions.

5.6.9 Time of Surgery and Development of PDPH

The results of this study showed that the incidence of PDPH was slightly lower (18.1%) in surgeries done at night as compared to daytime surgeries (27.4%). Though this difference was not statistically significant ($p = 0.13$). There isn't any subtle explanation for this finding, while previous studies have not been able to investigate this phenomenon. However, this provides an exciting opportunity for future research.

Although other factors might possibly be at play, these results point to a possible trend towards a higher incidence of PDPH in procedures performed during the day. One of the possible explanations would be that in MTRH, most students are present during the day and therefore there is more likelihood of more procedures being done by students as compared to night time. Previous studies have actually shown that there is a direct relationship between the qualifications of the person performing the procedure and the development of PDPH (Sadeghi, Patel, & Carvalho, 2021). Still, it's critical to exercise caution when interpreting this data and take into account any

confounding factors that can affect the relationship between time of surgery and development of PDPH. This finding is therefore not conclusive.

Regardless of the time of day, a number of factors could affect the likelihood of PDPH including personnel levels of training, patient caseloads, environmental conditions and differences in surgical techniques between daytime and nighttime. Additionally, patient characteristics like stress levels, sleep habits, and circadian rhythms may also be important in the development of PDPH after surgery and may warrant more investigations since there is no literature at the moment.

5.6.10 Number of attempts and Incidence of PDPH

The number of effective spinal block attempts and its correlation with the likelihood of developing PDPH were found to be statistically significant as risk factors determining occurrence of the condition. In our study, the probability of developing PDPH was significantly higher in situations where the spinal block was attempted for two or more times before success (32.4%) as opposed to cases where the block succeeded on the first try (18.5%). The statistical significance of the connection ($p = 0.029$) suggests a definite correlation between the number of attempts and PDPH. Consistent with the results of this investigation, (Al-Hashel et al., 2022) also documented an increased risk of PDPH following several subarachnoid punctures ($p=0.001$).

There seems to be a known association between the number of attempts and the development of PDPH going by previous research. For instance, (Ferede et al., 2021) noted that those who had repeated attempts during administration of spinal anaesthesia had 4.6 fold odds of developing PDPH as compared to those whereby success was achieved in the first attempt. As such, there is need to emphasize on

effective skills acquisition in order to ensure proficiency in administration of spinal anaesthesia to significantly reduce the risks of associated complications like PDPH.

In a nutshell, all previous studies have shown similar results just as with the size of spinal needles used for administration of anaesthesia. This trend has been documented by (Mekete et al., 2023), they found out that patients who had more than two tries had a roughly seven-fold increase in the chances of developing PDPH. In a similar vein, (Demilew et al., 2021) documented that PDPH risk increased dramatically with repeated efforts at spinal anesthesia.

5.4 Management and treatment outcomes of PDPH

5.4.1 Management of PDPH

It is worth noting that a lot is known about the risk factors for development of PDPH and the possible preventive measures but very little is known about other modalities of treatment apart from Epidural blood patch (EBP) which has been documented as the only known effective treatment for PDPH. A lot of controversies do exist on the effectiveness of various treatments and more research is still ongoing.

In this study, we evaluated the various treatments options, mainly analgesics, for treatment of PDPH and assessed the treatment outcomes. We noted that for those who developed PDPH, there wasn't documented diagnosis in the patient files and therefore this emphasizes the need for sensitization together with active follow up of all the patients who undergo spinal anaesthesia in our setting. Besides, we realized that there were no treatment protocols for PDPH at MTRH and that most of the analgesics prescribed were to treat postoperative pain but not primarily for the purposes of relieving the headaches.

Additionally, since there were no protocols on management of PDPH, none of the patients had any investigations carried out on them, whether laboratory or radiological investigations, aimed at ruling out other serious causes of headaches like infections or brain hemorrhages among others. A committee of expert's recommendation on assessment, prevention and management of PDPH (Uppal et al., 2023) recommended that Both CT scan brain and MRI brain to be appropriate for patients with new onset headaches.

According to the evidence provided, MRI of the brain with contrast is the more preferred imaging modality when available. In addition, where Cerebral Venous Sinus Thrombosis (CVST) is suspected, MRI venography or CT venography is indicated. Usually, spinal imaging is usually not needed not unless in cases of repeated headaches where it can show spinal abnormalities. However, there exists no treatment protocols in MTRH and therefore no investigations were carried out in all the patients. Also, we did not find a protocol for EBP in MTRH since the procedure is not commonly practiced in our setting. However, we did not inquire more as to the challenges and reasons behind not administering the treatment procedure despite previous data providing evidence on its effectiveness. From a recent study, (Shin, 2022) noted success rate of more than 93% without the need of repeat EBP whereby the headaches resolved with 2 days. All the same, EBP poses other complexities such as expertise, infrastructural and human resource support which may be a challenge in our setting. Still, the procedure doesn't come free of complications and caution is needed to prevent untoward outcomes like infections among other complications.

5.4.2 Analgesics for treatment of PDPH

Majority of patients (81.8%) in this study reported that analgesics were necessary to relieve PDPH symptoms, indicating the substantial discomfort that affected persons endured since the pains experienced were severe. These findings concur with (L. Kracoff & Kotlovker, 2016), highlighting the significance of pain treatment in PDPH cases to alleviate patient suffering and ensure better patient outcomes.

Nonetheless, despite majority of patients reporting that they needed analgesics for pain relief, a sizeable percentage (45.5%) did not take any analgesics at all. We did not go further to inquire the reasons as to why they did not seek any interventions but this could have been related to cost implications, individual believes and also health seeking behaviors amongst our study population.

For those that took analgesics for pain relief, Paracetamol was the most preferred option (40.9%). This could have been because of easy availability and also due to low costs of the drug which can easily be given over the counter without any prescription. (H. R. Choi, Fuller, & Bottros, 2020) highlighted the need for customized approaches to pain management and the unique nature of PDPH treatments in terms of diversity in analgesic use.

The analgesic options prescribed by the doctors from the inpatient treatment sheets and also discharge summaries were not explicitly directed toward treatment of PDPH since the diagnosis had not yet been made. Despite this, a range of analgesics were prescribed and administered, with NSAIDs being prescribed the most frequently (43.2%) with other combination prescriptions being NSAIDS + Opioids (25.0%), Paracetamol + Opioids (6.8%), Paracetamol + NSAIDS (4.5%) and the least prescribed combination being NSAIDS + Hyoscine at (2.3%). The results of this study therefore highlight the excessive use of NSAIDS singly while (Kracoff &

Kotlovker, 2016) in a review of suggested new treatments, recommend the need of a clinical practice that employs a multimodal approach to pain management in the treatment of PDPH.

(Patel et al. 2020) demonstrated and recommended the use of EBP in the treatment of PDPH due to its effectiveness as opposed to pharmacological therapies, though, in our setting we noted that no single patient was given the procedure as a treatment option. Other effective modalities that have been documented include epidural saline injections and other less invasive options like nerve blocks e.g. Sphenopalatine nerve blocks in combination with pregabalin (Verma et al., 2022) were not commonly practiced at MTRH.

However, there may be dangers associated with these procedures, therefore patient variables and procedural skill need to be carefully considered and this may be some among the reasons why those procedures were not given as treatment options, besides the fact that many clinicians may not have considered this problem to be an issue of major concern, since the headaches usually resolve after some time.

The results of this study do therefore highlight the gap in diagnosis and management of a rather common problem. During the study period, there were no laid out protocols on the management of the condition and so as to improve patient outcomes and reduce related morbidities, more investigation is needed into the best management approaches for PDPH in our setting.

5.4.3 Self-measures in management of PDPH

There were a range of interventions self-administered; the most popular ones being oral hydration, rest, and caffeine intake in combination. Most of the patients reported that they took coffee, rested and took oral fluids to relieve the headache (27.3%). However, it was not clear on the source of information on caffeine use to relieve the

headaches. Some reported that they got the information from the internet while others were advised by friends who worked in the healthcare sector. However, we did not set out to measure the effectiveness of those self-administered interventions in this study and therefore, this is an area worth more investigations in the future.

Rest and non-caffeinated fluids were selected by (25.0%) of patients, which indicates the role of hydration in the treatment of PDPH whereas rest and caffeine alone were selected by (20.5%) and (9.1%) of patients respectively. The use of cold water sponging was less common (2.3%), demonstrating the variety of self-management techniques among PDPH patients. It is also significant that only one (1) patient did not institute self-measures to relieve the headaches and this may point towards the importance of interventions to relieve the headaches for those who develop the condition.

These results are consistent with current guidelines for the conservative treatment of PDPH, which emphasize bed rest, hydration, and the use of analgesics to reduce pain (Kracoff & Kotlovker, 2016). The focus on rest and fluids underscores the significance of preserving euvolemia and reducing dehydration, both of which can worsen headache symptoms, especially those related to PDPH. Although coffee drinking was a popular self-measure, more research is needed to determine whether or not it is effective in treating PDPH since different literature has shown conflicting results. However, a recent study done in Rwanda (d'Amour, n.d., 2024) showed that use of caffeine supplements significantly conferred a great improvement in the intensity of PDPH.

On the other hand, compared to extended bed rest, (Arevalo-Rodriguez, Ciapponi, Roqué i Figuls, Muñoz, & Bonfill Cosp, 2016) noted that prompt ambulation may

lower the risk of PDPH. Their meta-analysis revealed a higher risk of PDPH in patients receiving bed rest; however, the quality of evidence was reduced as a result of study design constraints. Therefore, these divergent results highlight the difficulty in managing PDPH and the requirement for more investigation to clarify the best treatment modalities (both supportive and definitive) for better outcomes.

Although patients frequently use self-measures including rest, water, and caffeine consumption to relieve symptoms of PDPH, individual differences may exist in the efficacy of each treatment strategy.

In order to enhance patient outcomes, clinicians should take individual preferences into account and adjust care tactics accordingly, striking a balance between conservative measures and new research on alternative interventions. To improve the quality of care for patients with PDPH and to direct clinical practice, more research on the effectiveness of various self-management techniques is definitely required.

5.4.4 Treatment Outcomes of PDPH

We assessed the patients and categorized them into; 1. **Treatment failure**-where there was persistence of severe symptoms despite the measures undertaken; 2. **Incomplete relief**-where the symptoms were slightly reduced but there was no complete resolution of the headaches but the patients were able to cope and continue with their daily activities; 3. **Complete relief**-where all the symptoms subsided after initiation of the treatments.

In our study, we noted that 13.6% of patients had treatment failure and 65.9% of patients had incomplete remission of PDPH. However, following treatment, 20.5% of patients reported total remission of their headaches. This shows that PDPH patients responded differently to treatment and also that almost 80% of the patients did not get cured after all the interventions were instituted. The weakness with our study on

treatment outcomes was that we did not standardize the treatment modalities given since we did not seek to intervene during the study, since this was a cross-sectional observational study.

On the other hand, (Safa-Tisseront et al., 2001) examined the effects of EBP on 504 patients who had PDPH. They discovered that following EBP, 75% of patients got total relief, 18% had partial relief, and that only 7% had treatment failure. In comparison to the results of the current study, EBP therefore confers a higher rate of total relief and a lower rate of treatment failure. It is therefore necessary to acknowledge that EBP is a distinct intervention designed to address PDPH and there is the need to embrace this option in our setting.

Furthermore, (Youssef et al., 2021) pointed out that intravenous (IV) analgesics were used to treat patients who did not experience total relief following nerve block treatments; in certain circumstances, this was adequate to manage symptoms. This emphasizes how crucial it is to take into account additional or multimodal therapies for patients who do not fully recover from their initial therapy.

Overall, some studies show better results with particular interventions like EBP or nerve block procedures, but the current study's findings indicate a considerable proportion of patients with incomplete alleviation following numerous strategies for PDPH treatment and therefore pose a huge gap in formulation of treatment protocols and also the need for more research in our setting.

Previous data shows that PDPH usually clears within two days after initiation of EBP or spontaneously within one week if no interventions are given. However, recent data has shown persistence of headaches for over a month in some cases. In this study, we noted that PDPH headaches cleared up differently from patient to patient over time. A

proportion of patients saw a rather speedy resolution, as evidenced by the 5 (11.4%) of headaches that resolved within 24 hours after onset. A further 4 (9.1%) of headaches subsided within 24 to 48 hours, indicating that for most of the patients, the symptoms actually persisted for more than 48 hours.

Notably, around 11 (25%) of the headaches resolved in 48 to 72 hours, indicating that most of the patients had to bear with the symptoms for up to three days. This could ultimately have affected their recovery, postoperative ambulation and also interference of baby care for the obstetric mothers. In fact, given that some of those patients could have had additive pain from the surgical sites, the impact of those cumulative pains could have been immense.

On the other hand, the results showed that within 7 days, about 34 (77.3%) of headaches were relieved, which is consistent with the average period for PDPH resolution whereby most of the headaches are reported to disappear spontaneously within 5-7 days even without treatments (Azzi et al., 2022). Interestingly, a subgroup of patients with persistent or refractory symptoms for more than one week was identified, as 10 (22.7%) of cases had persistent headaches for more than one week. In a previous study, (Youssef et al., 2021), the effectiveness of various nerve block techniques for treating headaches revealed a noteworthy decline in headache Numeric Rating Scale (NRS) after administration of the blocks within a few hours during the course of the follow-up period.

When we compare for instance this study's outcomes with the outcomes noted after administration of nerve blocks, it becomes clear that nerve blocks significantly reduce headaches' severity scores in a relatively shorter period of time (within hours) compared to the conventional strategies currently being practiced in our setting,

whereby the headaches persist over a longer duration of time. More training and uptake of those techniques is therefore quite needed since they provide more instant relief from the headaches. In addition, since some headaches persisted for more than a week, there is need to conduct additional studies to investigate various available and feasible treatment options that offer better success in the management of refractory PDPH.

Across all the headache severity levels, Non-steroidal Anti-inflammatory Drugs (NSAIDs) were the most often prescribed analgesics. However, we noted that majority of the patients who experienced severe forms of headaches were those who had NSAIDs alone prescriptions (52.6%). This then raises the question whether NSAIDs are ineffective for treatment of PDPH or could the observations made have been due to other factors like adherence.

Therefore, for more severe headaches, analgesic combination therapy $\pm$ other treatment modalities should be preferred so as to increase the efficacy and also reduce side effects of individual drugs. This is because 15.8% of patients receiving NSAID prescriptions had mild headaches; 31.6% of them had moderate headaches and 52.6% of them had severe headaches.

On the other hand, the reverse was seen for NSAIDs + Opioids combination therapy whereby for those who received this prescription, majority of them experienced only mild headaches (54.5%). An important observation from this study was that for those who got NSAIDs+ Paracetamol + Opioids combination, they only experienced mild headaches (100%) and none of them got moderate or severe headaches. This underscore the efficacy of combination treatments in the management of PDPH but still highlights the need to tailor down the treatments to individual needs of the

patients and also the need for more research on the effectiveness of various treatment modalities.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATION

6.1 Conclusion

The incidence of PDPH at MTRH is 23.7% and this is higher than the recommended values of 1-14%. The number of attempts before a successful spinal block was statistically significant risk factor for development of PDPH. Most of the patients had severe headaches which started within 24 hours postoperatively and needed analgesics for relief of symptoms. Though the condition is common, the diagnosis is missed and there is no standardized protocol for management of the condition at MTRH.

6.2 Recommendations for practice.

- Continuous medical education (CME) for sensitization of all staff managing patients after spinal anaesthesia in surgical wards to create awareness on the condition so that diagnosis and management can be optimized.
- The hospital should consider procurement of pencil shaped spinal needles to substitute the quinckes (cutting-type) needles that are currently in use in MTRH. Also, there is need to advocate the use of smaller needle sizes so as to reduce the incidence of PDPH. Currently, only cutting-type needles are available at MTRH.
- MTRH to develop a protocol on diagnosis, prevention and treatment of PDPH including a multimodal strategy to pain management and approaches that mix analgesics and regional nerve blocks.
- There is need for further research in our setting to establish the real burden of the condition and also establish proper preventive strategies that are applicable in the setting of MTRH and also on efficacy of procedural therapies like nerve blocks and EBP, analgesics, self-measures and newer techniques of treatment.

- Emphasizing early symptom recognition and intervention by making patients aware of the possibility of developing headache after spinal anaesthesia, the anticipated time of onset and symptoms to be expected together with control techniques
- Since EBP is the only known definite treatment, a protocol should be developed for use in MTRH and proper training for anaesthesia providers be provided so as to gain the necessary skills to conduct the procedure.

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APPENDICES

Appendix I: Annexes.

Annex 1a. American Society of Anesthesiologist (ASA) Physical status Classification

Class I: A normal healthy patient

Class II: Any patient with mild systemic disease

Class III: Any patient with severe systemic disease that is not incapacitating

Class IV: A patient with incapacitating life-threatening disease

Class V: A moribund patient who is not expected to survive for 24 hours with or without the surgery

Class E: A patient undergoing an emergency operation (the 'E' added to the classification number)

Annex 1b: Criteria for post dural puncture headache (IHS)

Diagnostic criteria:

- A. Headache that worsens within 15 minutes after sitting or standing and improves within 15 minutes after lying, with at least one of the following and fulfilling criteria C and D:
 - 1. neck stiffness
 - 2. tinnitus
 - 3. hypacusia
 - 4. photophobia
 - 5. nausea
- B. Dural puncture has been performed
- C. Headache develops within 5 days after dural puncture
- D. Headache resolves either¹:
 - 1. spontaneously within 1 week
 - 2. within 48 hours after effective treatment of the spinal fluid leak (usually by epidural blood patch)

Note:

1. In 95% of cases this is so. When headache persists, causation is in doubt.
Adopted from Springer.com

Occurred after mobilization

Headache is aggravated by erect or sitting position and coughing, sneezing or straining

Relieved by lying flat/ supine position

Mostly localized in the occipital, frontal or generalized.

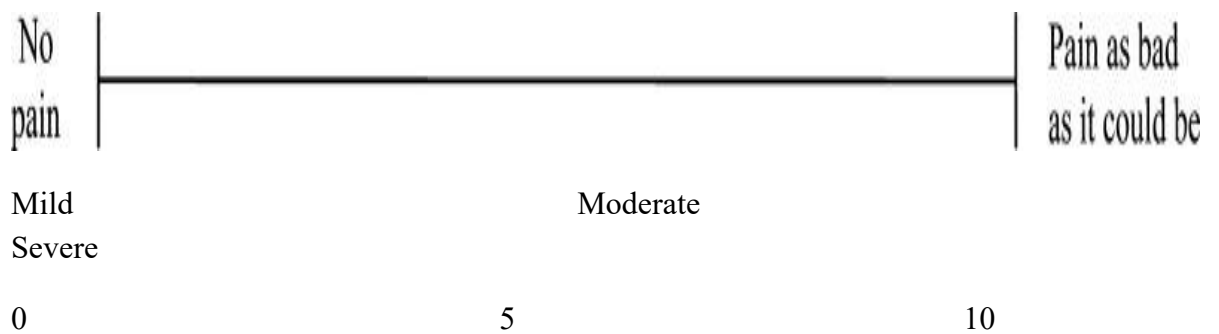
Annex 1c: Headache severity.

Mild: There is no limitation of activity

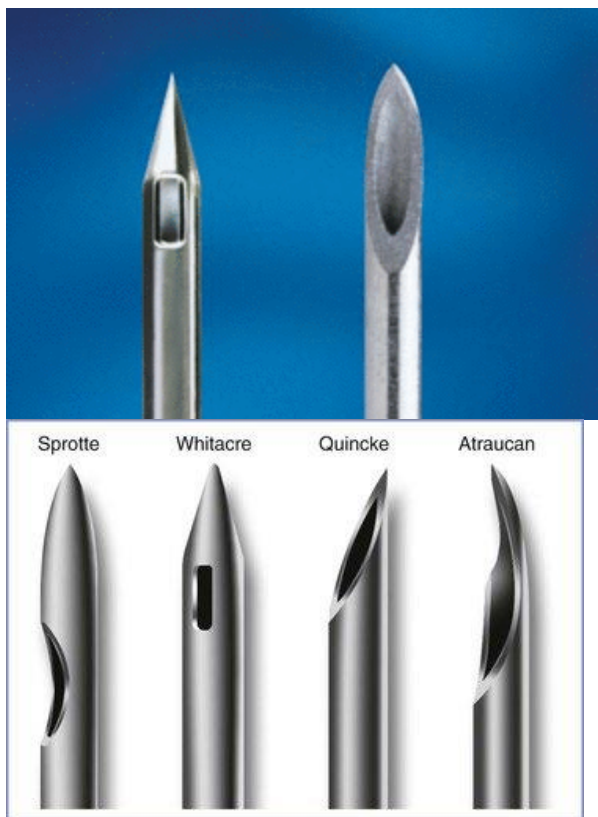
Moderate: There is limitation in activity and regular analgesics are required.

Severe: The patient is confined in bed, unable to perform daily activities.

Annex 1d: VAS for assessment of pain severity



Annex 1e: Spinal needles



Adopted from NYSORA

N.B. Quincke needle is the conventional traumatic type while sprotte, whitacre and Atraucan are the atraumatic spinal needles.

Annex1f: EBP Procedure

The procedure requires two clinicians; a consultant anesthetist or an experienced senior trainee should perform the epidural injection and a second clinician to do the venesection.

Cardiovascular monitoring and intravenous access may be considered to detect and treat bradycardia during the procedure.

The patient may be placed in the lateral or sitting position, considering the comfort of the patient in relation to her symptoms and the preference of the anesthetist.

The epidural injection should be performed at the same space or one space lower than the level at which the original dural puncture occurred.

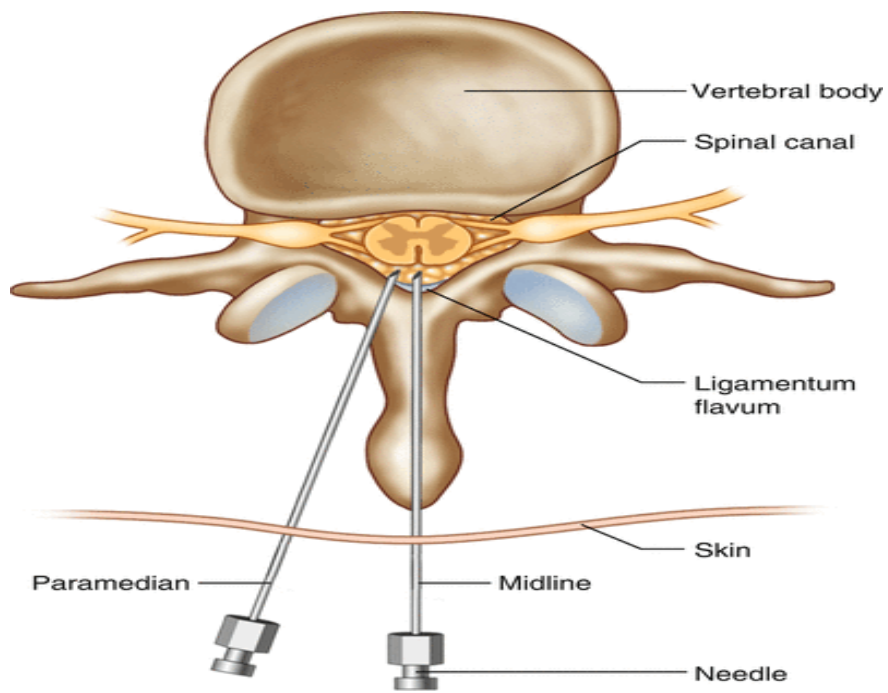
A full aseptic technique should be employed for both the epidural and component and venesection

The epidural space should be located before venesection is done.

After venesection, blood should be injected immediately into the epidural space through the epidural needle. Volumes of up to 20 milliliters of autologous blood are recommended if tolerated by the patient.

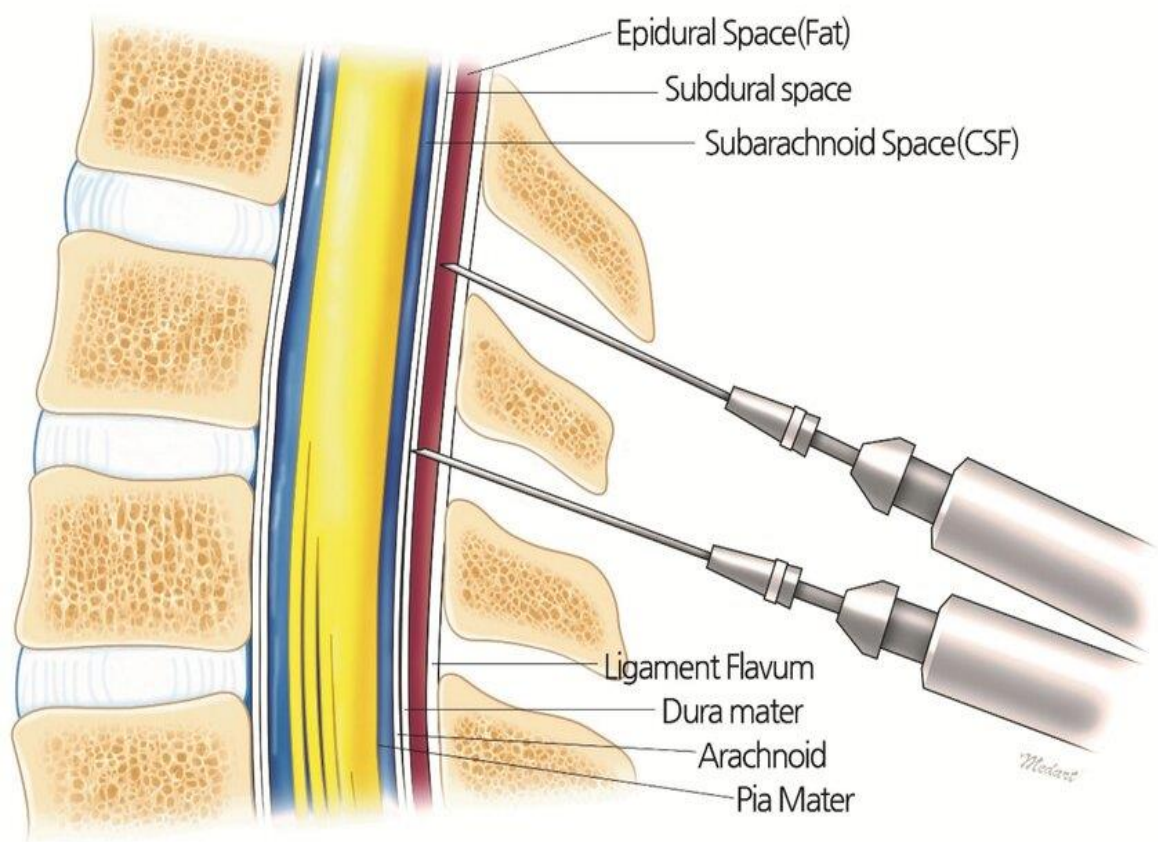
There is insufficient evidence to recommend the routine collection of blood for culture. The decision on whether to do so should remain with the individual clinician.

Annex 1g: spinal anaesthesia approaches.



Adopted from Springer.com

Annex 1h: anatomy of the epidural and subarachnoid spaces



Adopted from Research Gate

Annex1i: Treatment outcomes for PDPH

Failure: Persistent of severe symptoms to a point that the patient is unable to undertake their day to day activities

Complete relief: Complete resolution of all the symptoms after initiation of the intervention.

Incomplete relief: Resolution of severe symptoms such that the patient is able to undertake their day to day activities although there is still mild to moderate symptoms reported.

Appendix II: Consent Forms

Appendix IIa: English Informed consent form

My name is Dr. Jackson Mulei, a postgraduate student in Anaesthesia and Critical care at Moi University School of medicine (PGACC/01/17) and KMPDC registration A8991, Eldoret, Kenya, Telephone no. 0727084436. I am currently doing a study related to the surgery you have undergone. The following are details of the study before agreeing to participate in it.

Purpose of the Study:

The purpose of the study is to assess the incidence of post dural puncture headache following spinal anaesthesia at Moi Teaching and Referral Hospital, Eldoret.

What is PDPH?

This is the headache which can occur at any given time within two weeks after spinal anaesthesia. It is a common minor complication which the anesthetist aims to prevent at all times. Despite the many preventive strategies which are available, it can still occur and therefore the need for more research to establish the burden and alleviate future occurrences.

Rationale of the Study:

The incidence of PDPH after spinal anaesthesia is known in some hospitals elsewhere but we do not know the magnitude of the problem at MTRH. The findings of this study will therefore be used to suggest further means of reducing the incidence of PDPH.

Participation in the Study:

Your participation in this study will be voluntary and you can withdraw at any stage of the study without penalty. The study will be observational, no invasive interventions will be undertaken and there will be no costs or financial gains associated with participating in this study. Participation in this study will not interfere with the regular management before, during and after operation.

Confidentiality:

Your identity will be protected with utmost confidentiality during the study and only initials will be used in reference to the participants of the study.

Please sign below if you agree to participate in the study.

I have understood that to participate in this study, I shall volunteer information regarding my/my patient's illness and undergo medical examination. I am aware that I can withdraw from this study

at any given point without interference to my treatments at MTRH now or in the future. I have been assured that no injury shall be inflicted on me/my patient from my participation in this study. I have also been assured that all information shall be treated and managed with utmost confidentiality. I have not been induced or coerced by the investigator (or his appointed assistant) to consent for participation in this study.

Name of the participant.....

Signature.....

Date

PART 2: Kiswahili version Informed consent form

MAELEZO YA IDHINI

Mtafiti: Kwa majina ni Dkt. JACKSON MULEI ambaye amehitimu na kusajiliwa na bodi ya madaktari yaani KMPDB. Kwa sasa mimi ni mwanafunzi wa shahada ya uzamili katika spesheli ya Anesthesia na matibabu ya wagonjwa mahututi katika chuo kikuu cha Moi hapa mjini Eldoret.

Ningetaka kusajili wewe /Mpendwa wako katika utafiti ninaofanya ambao unaangazia tukio la maumivu ya kichwa baada ya upasuaji ambayo yanasababishwa na dawa zakuwezesha upasuaji ambazo zinapeanwa kupitia njia ya uti wa mgongo, katika hospitali ya rufaa ya MTRH.

Kusudi: Utafiti huu utaangazia uwepo na uzito wa janga hili la maumivu ya kichwa baada ya kupewa dawa za kuwezesha upasuaji kupitia kwa mgongo na pia kuweza kubaini mambo yanayofanya mgonjwa kupata shida hilo.

Utaratibu: Wagonjwa ambao watapata dawa za kuwezesha upasuaji kupitia sindano ya mgongo na ambao watakubali kusajili wakati wa utafiti huu, watapeana ujumbe kuhusu vile wanavyoendelea baada ya upasuaji ili kuweza kubaini kama watapata hayo maumivu ya kichwa. Wataweza kuelezea pia kuhusu matibabu watakayopata iwapo watakabiliwa na shida hilo. Wasajili pia watakuwa na ruhusa ya kujiondoa wakati wowote utafiti huo unapoendelea.

Faida: Hakutakuwa na faida kwa mtu binafsi kwa kushiriki katika utafiti huu. Pia, hakutakuwa na hatari yoyote inayotarajiwa kutokana na kushiriki katika utafiti huu.

Usiri: Habari zote kuhusu mgonjwa zitakazonakiliwa wakati wa utafiti zitawekwa kwa usiri mkubwa na wala hazitatolewa kwa mtu yeyote asiyehusika na utafiti huu.

Nimeelewa kuwa kushiriki katika utafiti huu, kwa hiari nitatoa habari kuhusu maradhi yangu / ya mgonjwa wangu na uchunguzi wakimatibabu utafanywa. Ninafahamu kuwa ninaweza kujiondoa kutoka utafiti huu wakati wowote bila kuathiri haki yangu / mgonjwa wangu katika MTRH sasa na hata baadaye. Nimehakikishiwa ya kwamba hakuna madhara yoyote yatakayoathiri mimi / mgonjwa wangu kutokana na kushiriki katika utafiti huu. Nimehakikishiwa kuwa taarifa zote zitawekwa na kusimamiwa kwa

siri. Ninahakikisha ya kwamba sijalazimishwa na mchunguzi mkuu (au msaidizi wake) kupeana kibali kushirikishwa katika utafiti huu.

Jina la mshiriki.....

Sahihi.....

Tarehe

Appendix III: Questionnaire**Section A: Patient Identification**

Serial No.....In patient No.....

Contact telephone No.....

Date.....

Section B. Social and demographic Data

Date of birth.....Sex.....

WeightHeight.....BMI.....

County of residence.....

Religion; Christian..... Muslim..... Others.....

Level of Education (Tick as appropriate)

Elementary	
High school	
College	
University	
Masters	

Any history of smoking or drinking..? YES OR NO (Tick as appropriate)

	YES	NO
Smoking		
Drinking		

Previous History of Spinal anaesthesia: Yes..... No..... (Tick as appropriate)

If Yes above; any history of post dural puncture headache? Yes.....

No.....

Section C. Operating theatre Data

ASA Classification

I	
II	
III	
IV	
Not documented	

Type of surgery (Tick as appropriate)

Emergency Surgery	
Elective surgery	

Length of surgery (To be extracted from the anaesthetic charts)

Less than 2 hours	
Between 2 hours and 4 hours	
More than 4hrs	

Specialty..... (Tick as appropriate)

Obstetrics	
Orthopedics	
General surgery	
Urology	
Others... specify	

Any premedication given? Yes..... No.....

If Yes above; Please explain drugs given and doses (from the anaesthetic charts)

.....

Date and time when the Spinal anaesthesia was given (from the anaesthetic chart)

Date.....

Time.....

Not documented.....

Spinal needle Used: (a) Type (Design)..... (b) Size.....

Not documented (specify)

Approach to the spinal anesthesia (Tick only where appropriate)

Midline.....

Paramedian.....

Others; specify.....

Number of dural puncture attempts; 1 attempt..... ≥ 2

attempts..... Not documented.....

Section D. Follow up data in Hospital

New onset headaches present? Yes..... No.....

If yes above, what are the associated/aggravating factors?

.....

Are there any relieving factors? Please specify.

.....

Date and time of onset of headaches:

Date..... Time:

Time of onset of the headaches, with reference to end of surgery, if applicable

Within 24hrs.....

24hrs to 48 hrs.....

48hrs to 72hrs.....

After 3 days.....

Within 7 days

Severity of the headaches as per the VAS

Mild.....

Moderate....

Severe.....

What measures do you take to relieve your headache? (Tick where appropriate)

Take rest.....

Fluid diet.....

Caffeine/Tea.....

Any other measures (please specify)

.....
.....

Do you need analgesics to relieve the pains? Yes.....

No.....

Analgesic options/Drugs administered:

Drug		
	Yes	No
Paracetamol		
Diclofenac		
Ibuprofen		
Opioids (Specify)		
Others (Specify)		
Not documented		

Document Analgesics/other treatments prescribed by the clinicians:

.....

Outcomes/Effectiveness of the treatment given: (Tick as appropriate)

Complete relief (Disappearance of all symptoms) ☐

Incomplete relief (Clinical improvement, able to perform daily activities) ☐

Failure (Persistence of severe symptoms) ☐

SECTION E: Resolution of headache

Time of when patient reports that the headaches resolved with reference to the time of headache onset

Within 24hrs.....

24hrs to 48 hrs.....

48hrs to 72hrs.....

After 3 days.....

Within 7 days

Headaches persisting more than seven (7) days (tick as appropriate)

YES	
NO	

Appendix IV: IREC Approval Letter



MTRH/MU-INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)
MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471023



MOI UNIVERSITY
COLLEGE OF HEALTH SCIENCES
P.O. BOX 4606
ELDORET
Tel: 33471023
10th August, 2022

Reference: IREC/209/2022
Approval Number: 0004210

Dr. Jackson Mulei Kamanzi,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA

Dear Dr. Mulei,

HOSPITAL INCIDENCE AND MANAGEMENT OF POSTDURAL PUNCTURE HEADACHE IN PATIENTS UNDERGOING SPINAL ANAESTHESIA AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET

This is to inform you that **MTRH/MU-IREC** has reviewed and approved the above referenced research proposal. Your application approval number is **FAN: 0004210**. The approval period is **10th August, 2022- 9th August, 2023**. This approval is subject to compliance with the following requirements;

- i. Only approved documents including (informed consents, study instruments, Material Transfer Agreements (MTA) will be used.
- ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by **MTRH/MU-IREC**.
- iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to **MTRH/MU-IREC** within 72 hours of notification.
- iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to **MTRH/MU-IREC** within 72 hours.
- v. Clearance for export of biological specimens must be obtained from **MOH at the recommendation of NACOSTI** for each batch of shipment.
- vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
- vii. Submission of an executive summary report within 90 days upon completion of the study to **MTRH/ MU-IREC**.

Prior to commencing your study, you will be required to obtain a research license from the National Commission for Science, Technology and Innovation (NACOSTI) <https://oris.nacosti.go.ke> and other relevant clearances from study sites including a written approval from the CEO-MTRH which is mandatory for studies to be undertaken within the jurisdiction of Moi Teaching & Referral Hospital (MTRH) and its satellites sites.

Sincerely,



PROF. E. WERE
CHAIRMAN

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE

10 AUG 2022

APPROVED

cc	CEO - MTRH	Dean - SOP	Dean - SOM
	Principal - CHS	Dean - SON	Dean - SOD

Appendix V: MTRH Approval to Conduct Research



An ISO 9001:2015 Certified Hospital



MOI TEACHING AND REFERRAL HOSPITAL

Telephone: (+254)053-2033471/2/3/4
 Mobile: 722-201277/0722-209795/0734-600461/0734-683361
 Fax: 053-2061749
 Email: ceo@mtrh.go.ke/directorsoffice@mtrh@gmail.com

Nandi Road
 P.O. Box 3 – 30100
 ELDORET, KENYA

Ref: ELD/MTRH/R&P/10/2/V.2/2010 10th August, 2022

Dr. Jackson Mulei Kamonzi,
 Moi University,
 School of Medicine,
 P.O. Box 4606-30100,
ELDORET-KENYA.

HOSPITAL INCIDENCE AND MANAGEMENT OF POSTDURAL PUNCTURE HEADACHE IN PATIENTS UNDERGOING SPINAL ANAESTHESIA AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET

You have been authorised to conduct research within the jurisdiction of Moi Teaching and Referral Hospital (MTRH) and its satellites sites. You are required to strictly adhere to the regulations stated below in order to safeguard the safety and well-being of staff, patients and study participants seen at MTRH.

- 1 The study shall be under Moi Teaching and Referral Hospital regulation.
- 2 A copy of MTRH/MU-IREC approval shall be a prerequisite to conducting the study.
- 3 Studies intending to export human bio-specimens must provide a permit from MOH at the recommendation of NACOSTI for each shipment.
- 4 No data collection will be allowed without an approved consent form(s) to participants unless waiver of written consent has been granted by MTRH/MU-IREC.
- 5 Take note that data collected must be treated with due confidentiality and anonymity.

The continued permission to conduct research shall only be sustained subject to fulfilling all the requirements stated above.

The approval period is 10th August, 2022 – 9th August, 2023.

[Signature]
DR. WILSON K. ARUASA, MBS, EBS
 CHIEF EXECUTIVE OFFICER
MOI TEACHING AND REFERRAL HOSPITAL

C.C. - Senior Director, Clinical Services
 - Director, Nursing Services
 - HOD, HRISM

MOI TEACHING AND REFERRAL HOSPITAL
 CEO
 APPROVED
 10 AUG 2022

SIGN.....
 P. O. Box 3-30100, ELDORET

All correspondence should be addressed to the Chief Executive Officer
 Visit our Website: www.mtrh.go.ke
 TO BE THE LEADING MULTI-SPECIALTY HOSPITAL FOR HEALTHCARE, TRAINING AND RESEARCH IN AFRICA

Appendix VI: Budget

Item	Quantity	Unit cost Kshs	Total Kshs
Measuring board	1	3000	3000
Research assistants training and expenses	1	40,000	40,000
Biostatistician	1	30,000	30,000
Printing	Multiple	20,000	20,000
Questionnaire	Once	10,000	10,000
Flash disc	1	5000	5000
Marker pens	5	50	250
Folders	100	60	6000
Box files	10	800	8,000
Paper punch	1	500	500
Stapler	2	300	600
Staples	3 packets	100	300
Biro pens	2 dozens	250	500
Pencils	1 dozen	300	300
Erasers	1 dozen	250	250
Airtime/ internet bundles	3 months	3000 per month	9,000
Note books	12 pieces	100	12,000
Telephone	1	5,000	5,000
Correspondence with publishing journal	1	40,000	40,000
Miscellaneous 10% of the total cost			19,070
Grand total			209,770